**Department of Health and Human Services**
Health Resources and Services Administration

# *1997 Report of Center Specific Graft and Patient Survival Rates*

## *Executive Summary*



United Network for Organ Sharing

# 1997 REPORT

# OF

# CENTER SPECIFIC

# GRAFT AND PATIENT

# SURVIVAL RATES

## EXECUTIVE SUMMARY

This report was prepared by the United Network for Organ Sharing (UNOS)
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Health Resources and Services Administration, Office of Special Programs,
Division of Transplantation;
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and the U.S. Scientific Registry of Transplant Recipients

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# PREFACE

The United Network for Organ Sharing (UNOS) operates the national Organ Procurement and Transplantation Network (OPTN) and the national Scientific Registry of Transplant Recipients. In this role, UNOS functions as both a contractor for the Federal Government and as a private, non-profit corporation. Under contract with the Health Resources and Services Administration, UNOS has operated the OPTN since September 30, 1986, and the Scientific Registry since September 30, 1987.

Under the terms of the Transplant Amendment Act of 1990, UNOS is required to determine center specific transplant survival rates for all solid organ transplants performed within the United States and provide this information to the Division of Transplantation. This *1997 Report of Center Specific Graft and Patient Survival Rates* represents the third biennial report, based largely on scientific Registry data, compiled and analyzed from January 1, 1988, through April 30, 1994.

There are 7 volumes in this report: 6 Organ Specific Volumes and 1 Executive Summary. The *organ specific volumes* contain a summary of the national graft and patient survival outcomes for each organ, as well as a description and distribution of the donor and recipient characteristics among programs. Also included in each organ specific volume is an *User's Guide* which provides guidance on how to read the data and use the report. The *Executive Summary* condenses the primary results from each organ specific volume and describes the technical methods used in creating this report.

## SUGGESTED CITATION FOR THIS REPORT

1997 Report of Center Specific Graft and Patient Survival Rates, UNOS, Richmond, VA, and the Division of Transplantation, Office of Special Programs, Health Resources and Services Administration, U.S. Department of Health and Human Services, Rockville, MD.

**Suggested Abbreviated Citation**

1997 Center Specific Report. UNOS; DOT/HRSA/DHHS.

**Publications based upon UNOS data in this report or supplied upon request must include the above citation as well as the following statement:**

The data and analyses in the *1997 Report of Center Specific Graft and Patient Survival Rates* have been supplied by UNOS. The authors alone are responsible for the reporting and interpretation of these data.

# ACKNOWLEDGMENTS

The data in this report were provided on a voluntary basis by transplant programs, histocompatibility laboratories and organ procurement organizations throughout the United States. The United Network for Organ Sharing (UNOS) gratefully acknowledges the efforts of program directors, administrators, data coordinators, and other transplant professionals, whose efforts have made it possible to compile and analyze transplantation data collected across the nation.

This report has been compiled through the collective efforts of many individuals. For their assistance, UNOS thanks Judith Braslow, Gwen Mayes, and Remy Aronoff of the Division of Transplantation, Office of Special Programs, Health Resources and Services Administration, U.S. Department of Health and Human Services.

UNOS also appreciates the guidance and advice provided by the Technical Oversight Subcommittee of the Scientific Advisory Committee, in particular, Steve Belle, Ph.D., Dennis E. Daniels, Ph.D., David Gjertson, Ph.D., Lawrence G. Hunsicker, M.D., Jeffrey D. Hosenpud, M.D., Charles F. Shield, III, M.D., and David E.R. Sutherland, M.D., Ph.D. For their suggestions and critical review of this report, we also wish to thank Barbara Bernhard, Steve Bynon, M.D., John M. Holman, Jr., M.D., Ph.D., Anne Carothers Kay, George B. Mallory, Jr., M.D., Lawrence F. McManus, M.D., Paul Oldam, Kevin Stump, R.N., B.S.N., Deborah C. Surlas, R.N.

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# TABLE OF CONTENTS

**VIII. Heart-Lung Chapter**



**IX. Technical Methods**

# LIST OF TABLES AND FIGURES

**Technical Methods**

*Figure Number*

# I. OVERVIEW

**Introduction**
**Project Development**
**Uses of the Report**
**What to Remember When Using the Report**
**Additional Resources**

# I. OVERVIEW

## A. INTRODUCTION

*The 1997 Report of Center Specific Graft and Patient Survival Rates* (hereafter referred to as the Report) is produced by the United Network for Organ Sharing (UNOS), Richmond, Virginia. UNOS operates the national Organ Procurement and Transplantation Network (OPTN) and the national Scientific Registry for Transplant Recipients under contracts with the Division of Transplantation, Office of Special Programs, Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services.

Under the terms of the Transplant Amendment Act of 1990, UNOS is required to determine program specific transplant survival rates for all solid organ transplants performed within the United States. This report is the third center specific transplant survival study performed to fulfill this contractual arrangement. In addition, this report is intended to provide updated information on national and program specific survival outcomes, and to enhance the awareness of transplant program performance in the United States. Such awareness is vital to promote the continued improvement in transplant outcomes.

The *1991 Report of Center Specific Graft and Patient Survival Rates* was based on all solid organ transplants between October 1, 1987, and December 31, 1989. The 1994 report was based on solid organ transplants between October 1, 1987, and December 31, 1991. The current Report includes U.S. transplant data from January 1, 1988, through April 30, 1994. This cohort was chosen to capture the maximum number of transplants with sufficient follow-up data. Specifically, the Report:

- Presents data for 97,587 transplant procedures performed on 92,966 patients at 742 separate transplant programs during the study period.

- Considers patient and donor characteristics for each organ specific risk model (see organ specific chapters for list of characteristics).

- Emphasizes short term as well as long term survival. Short term survival is defined at two time points -- 3 months (1 month for thoracic organs) and 1 year following transplant. Long term survival is defined in two ways: (1) survival at 3 years post-transplant, and (2) survival at 3 years post-transplant for those patients (grafts) who were living (still functioning) at 1 year post-transplant. Throughout this report, the second definition will be referred to as **conditional 3 year survival**. *The conditional 3 year survival analysis assesses characteristics independent of those limited to the first year (e.g., the risk of surgical procedures and early acute rejection events).*

  Note that the *conditional* 3 year survival rate often may be greater than the 1 year survival rate. This does not mean that the unconditional 3 year survival rate is also greater than the one year survival rate. In fact, the latter cannot exceed the 1 year survival rate.

- Presents both **actual** and **expected** graft and patient survival rates.

- Shows survival rates for two eras. Era 1 is from January 1, 1988, to April 30, 1992. Era 2 is from May 1, 1992, to April 30, 1994. *Era-specific survival rates allow the assessment of the improvement in a program's performance over time. The 3 year survival analysis is possible only for Era 1, due to insufficient follow-up on patients who received transplants in Era 2.*

Due to small numbers of these types of transplants, the following were excluded from the analyses:

- data on multi-organ transplants other than kidney-pancreas and heart-lung transplants,

- heterotopic heart transplants, and

- living donor transplants other than living donor kidney transplants.

As with previous editions, this report contains:

- Organ Specific Volumes -- Kidney, Liver, Pancreas, Heart, Lung, and Heart-Lung
- Executive Summary

*The organ specific volumes* contain (1) a User's Guide, which provides guidance on how to use the

report and interpret the data tables, (2) a summary of the national graft and patient survival outcomes for each organ, and (3) transplant program specific data: a table of survival rates, a chart describing the distribution of characteristics for the transplant program and the nation, and an optional narrative for every authorized transplant program in the United States. *The Executive Summary* condenses the primary results from each organ specific volume and describes the technical methods used in creating this report. It is organized as follows:

1. Overview -- Covers the development and scope of this report.

2. Data Highlights -- Provides a brief summary of the results and conclusions across all organs.

3. Organ Specific Results -- Presents in six chapters the summarized results from the organ specific analyses. By design, the contents and language of each chapter are similar. Each chapter includes a synopsis of the completeness of the data, the numbers of transplants and outcomes studied, overall survival rates, the distribution of survival rates among programs, a description and distribution of the characteristics among programs, and a summary section.

4. Technical Methods -- Describes in detail the statistical methods used to report graft and patient survival rates.

Glossary of Terms

The general terms and definitions used throughout this report can be found in the User's Guide (Chapter 1) in each organ specific volume.

## B. PROJECT DEVELOPMENT

The UNOS Scientific Advisory Committee (SAC) developed the project plan for this report. An Ad Hoc Technical Oversight Subcommittee of the UNOS SAC, including HRSA staff, was established to provide guidance for the project design and subsequent data analysis. (The Technical Methods Chapter provides a list of the members of this Subcommittee.) Then, UNOS research staff conducted the study.

The project plan consisted of the following elements:

1. Outcomes from all organ kidney, liver, pancreas, heart, lung, and heart-lung transplants performed from January 1, 1988, through April 30, 1994, were analyzed. Because there were not enough multi-organ transplants to draw significant statistical findings by themselves, all but kidney-pancreas and heart-lung were excluded from this analysis. For similar reasons, heterotopic heart transplants and living donor heart, liver, and pancreas transplants were also excluded.

2. Logistic regression, a statistical method used for risk modeling, was applied to calculate each transplant program's expected graft and patient survival rates. A set of organ specific donor and recipient characteristics recommended by the Ad Hoc Technical Oversight Subcommittee was initially included in the mathematical modeling procedure. Then using backward elimination, the final models would contain those that had the strongest impact on survival outcomes (see the Technical Methods Chapter).

3. Actual and expected graft and patient survival rates were determined for each transplant program at:

   - 1 month for heart, lung, and heart-lung transplants, 3 months for kidney, liver, and pancreas transplants -- to assess mortality risk from the surgical procedure, or to assess early graft failure or rejection.

   - 1 year for all organs -- to assess short term survival and rejection or graft failure.

   - 3 years for all organs -- to assess long term survival and rejection or graft failure. Three year survival rates are presented in two ways: (1) as survival at 3 years after transplantation, and (2) *conditional 3 year survival*, or survival at 3 years post-transplant for those patients (grafts) who were living (still functioning) at 1 year post-transplant.

4. Each transplant program received a copy of their data and preliminary survival results for validation. If a transplant program agreed that the results reflected its performance during the study period, the transplant program had the option not to validate its data. Otherwise, the data were validated by the transplant program in order to assure that accurate and complete data

were used in the study. If the transplant program made corrections on the cadaveric donor or histocompatibility data, Organ Procurement Organizations and Tissue Typing Laboratories were asked to re-verify these corrections.

5. Each transplant program's final survival results in this report are based on the validated data. Each transplant program was given the opportunity to write a one-page narrative to provide additional information that they felt might have had an impact on their survival rates. These narratives were published unedited, alongside the program's graft and patient survival rates, in each organ specific volume.

6. Two separate national kidney long term survival models are presented in the Kidney Chapter of the Executive Summary and the Summary Chapter of the Kidney Volume. In addition to the variables selected for the first model, the second model included two post-transplant variables: delayed graft function (defined as whether a patient needed dialysis in the first week after transplant), and presence of rejection events (defined as whether a patient experienced rejection episodes within the first six months following transplant). This is because these two variables have been demonstrated in the past to play important roles in long term survival. However, these variables also may be highly related to practices at individual transplant programs. Therefore, in calculating expected survival rates for a given transplant program, the first model was applied instead of the second, which might adjust for a possible center effect expressed within these two variables.

## C. USES OF THE REPORT

Potential transplant candidates and their family members commonly use this report to learn about transplantation and assess transplant programs. The data contained in the report are particularly helpful in combination with other resource information available from UNOS, such as patient brochures and general statistics on organ donation and transplantation.

Outcome data in this report also are valuable to researchers in a variety of settings, including academic research departments, hospital planning and development, and managed care organizations. Such information can help researchers analyze transplant services.

The report also has been used as a resource by journalists preparing news stories on transplant topics. *However, it must be noted that the report is not intended to rank transplant programs based on outcome, nor to compare the actual performance of programs relative to one another.* The most appropriate comparison is of an individual program's *actual* survival outcomes relative to its *expected* outcomes.

UNOS and the transplant community also have used the report data as a continuous quality improvement tool. This began in 1992 when the UNOS Membership and Professional Standards Committee, in conjunction with UNOS staff, developed an objective method for determining which programs should be investigated due to poor (lower than expected) performance. Specifically, the method uses this report to identify potential "poor performance" programs, and then re- evaluates these programs *using more recent data.* Both statistical and clinical significance are important components of this method, which set for *actual* program survival rates a threshold deviation from their *expected* rates. Specifically:

- *-10% for deviations which are highly statistically significant (p-value close to zero), or*

- *-35% for deviations which are not statistically significant (p-values close to one) but are considered to be clinically significant.*

Using this standard through a continuous quality improvement process is not intended to be punitive, but rather allows UNOS to identify, in a reasonable way, what is fair across a wide variety of programs and to determine those for which further review is indicated.

## D. WHAT TO REMEMBER WHEN USING THE REPORT

In this report, each transplant program's data are summarized in three ways:

1. Graft and patient survival rates table -- presents both the actual and expected graft and patient

survival rates at 1 month (thoracic organs) or 3 months, 1 year, and 3 years.

2. Donor and recipient characteristics table -- displays a comparison of the transplant program's patient and donor characteristics with the national overall data.

3. Optional written narrative from transplant program -- describes the transplant program's understanding of their graft and patient survival rate data.

When using the report, you should remember that:

- Caution should be exercised in comparing one program to another because each program may reflect a special patient and donor pool. Conclusions should be based not only on the survival rate tables but also on the patient and donor characteristics tables and the optional narrative provided by the transplant program.

- By themselves, the **actual** survival rates may be misleading because the actual survival rates are reflective of both the quality of the services at a program and the characteristics of the patients being treated by that program.

- The **expected** survival rates show what survival rates are to be expected at a program if its patient and donor characteristics are taken into account. However, not all of the characteristics affecting graft and patient survival were included in the analysis. *There may be other characteristics which have an impact on survival rates that were not included in this report.*

- For the large majority of transplant programs, the difference between the actual and expected survival rates was not statistically significant.

- The number of transplants performed at a program is an important characteristic to consider when evaluating survival rates. In general, the more transplants a program has performed, the more closely the survival rates reflect the quality of the program.

Patients and their families also should consider the following characteristics in selecting a transplant program:

- The experience, training, and education of the transplant team and the medical and nursing care available throughout the process, from candidate evaluation through transplantation and follow-up care.

- The costs of the transplant procedure, physician services, hospitalization, and medications.

- The proximity of the transplant program to home and how easily it can be reached.

- The friends and family available for assistance before, during, and after the transplant.

- The quality and availability of post-transplant services.

## E. ADDITIONAL RESOURCES

**Personal Physician** -- One of the most valuable resources for interpreting the data in the *1997 Report of Center Specific Graft and Patient Survival Rates* is a personal physician. Even if the physician does not have a copy of the report, he or she should be able to explain the differences between the types of data reported for the specific transplant programs of interest.

**The Transplant Program** -- Information about a transplant program's graft and patient survival rates should be available upon request of the transplant program. You might seek assistance from the transplant surgeon or physician, transplant coordinator, or social worker.

**National Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients** -- UNOS maintains the OPTN and the Scientific Registry and can be contacted for information about the report and for assistance with data interpretation. Please contact:

| | |
|---|---|
| All ***Patient*** inquiries: | (888)TXINFO-1 |
| Research inquiries: | UNOS Data Request Line -- 804/330-8576 or 804/323-3794 (fax) |
| Media inquiries: | (804) 327-1432 |

UNOS also maintains a **Web site** on the Internet from which visitors can retrieve the latest UNOS statistics, patient information, press releases, policies

and by-laws, and other information pertinent to transplant professionals, the media, and the general public. The address is: www.unos.org.

UNOS also is producing the *1997 Report of the OPTN: Waiting List Activity and Donor Procurement*. The purpose of this report is to provide information relating to donor procurement and waiting list activity, including median waiting times to transplant and percentage transplanted for the U.S. as well as each UNOS region and every OPO. Used in conjunction with the *1997 Report of Center Specific Graft and Patient Survival Rates*, patients and their families will have information on donor procurement rates and estimated waiting time to transplant given various patient clinical or demographic characteristics for each OPO and waiting list activity data for transplant centers within each OPO.

UNOS also has resource packets available for transplant patients or family members. These packets include brochures on the organ allocation process and questions patients should ask a transplant program, information on financial issues for transplant patients, summary transplant statistics and details on obtaining more specific information from UNOS.

Beginning in 1998, transplant centers will provide a resource packet to every patient accepted for transplantation. In addition, UNOS maintains a toll-free request line (1-888-TXINFO-1) for anyone wishing to receive this information separately.

**The Federal Government** -- The *1997 Report of Center Specific Graft and Patient Survival Rates* was prepared by UNOS under contract with the U.S. Department of Health and Human Services, Health Resources and Services Administration, Office of Special Programs, Division of Transplantation. For information on how to obtain a copy of the report, or additional information regarding transplantation, contact:

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Office of Special Programs
Division of Transplantation
5600 Fishers Lane
Parklawn Building., Room 7-29
Rockville, Maryland 20857 USA
(301) 443-7577

# II. DATA HIGHLIGHTS

Numbers of Transplants, Patients, and Programs
Completeness of Follow-up Data
National Graft and Patient Survival Rates
Differences in Actual and Expected Survival Rates
Overall Donor and Recipient Characteristics
Characteristics Affecting Survival Outcomes
Conclusions

# II. DATA HIGHLIGHTS

## A. NUMBERS OF TRANSPLANTS, PATIENTS, AND PROGRAMS

There were 97,587 transplants performed for 92,966 patients at 742 programs between January 1, 1988, and April 30, 1994 (see Table II-1). The entire transplant cohort was used to determine graft and patient survival rates at 3 months (1 month for thoracic organs) and 1 year. A subset of this cohort (i.e., transplants performed between January 1, 1988, and April 30, 1992) was used to calculate survival rates at 3 years. Three year survival rates were determined in two ways:

1. Unconditional survival at 3 years post-transplant.
2. **Conditional 3 year survival**, defined as survival at 3 years for those who survived at least 1 year post-transplant.

The emphasis on long term survival in this report is on the conditional 3 year survival rates because the conditional analysis assesses characteristics independent of those limited to the first year, such as the risk of surgical procedures.

**Table II-1. Number of Transplants, Patients, and Transplant Programs**

| Organ | Number of Transplants | Number of Patients | Number of Programs |
|---|---|---|---|
| KI | 62,572 | 60,340 | 249 |
| LI | 16,658 | 14,607 | 103 |
| PA | 3,222 | 3,142 | 96 |
| HR | 12,627 | 12,428 | 161 |
| LU | 2,135 | 2,079 | 75 |
| HL | 373 | 370 | 58 |
| Total | 97,587 | 92,966 | 742 |

## B. COMPLETENESS OF FOLLOW-UP DATA

Completeness of graft and patient follow-up data for 1 year and conditional 3 year survival is shown in Table II-2. If the status of a patient (graft) was known at the end of a specified time interval, then that observation was said to have complete follow-up data at the end of that interval. For example, the time interval for the conditional 3 year analysis is from 1 year to 3 years after transplantation. Thus, complete follow-up data would indicate a known status, either that the patient was still alive (graft was still functioning) at 3 years post-transplant, or that the patient died (graft failed) between 1 and 3 years post-transplant.

As Table II-2 shows, more than 98% of 1 year graft follow-up data and more than 96% of 1 year patient follow-up data were complete. For conditional 3 year survival, more than 91% of both graft and patient follow-up data were complete. Abdominal organ recipients had lower levels of complete 1 year follow-up data. This may be due to higher retransplantation rates for these organs. Additionally, with kidney or pancreas failure, patients might survived by being returned to dialysis or exogenous insulin administration and thus could be subsequently lost to follow-up.

**Table II-2. Completeness of Graft and Patient Follow-up Data**

| Organ | 1 Yr FU[1] (%) | | Cond. 3 Yr FU[2] (%) | |
|---|---|---|---|---|
| | Graft | Patient | Graft | Patient |
| KI | 98.3 | 96.5 | 91.7 | 91.9 |
| LI | 99.1 | 98.5 | 96.8 | 96.5 |
| PA | 99.3 | 96.5 | 93.9 | 94.4 |
| HR | 98.9 | 98.9 | 98.0 | 97.9 |
| LU | 98.7 | 98.6 | 95.4 | 95.2 |
| HL | 98.1 | 98.1 | 96.7 | 96.7 |

[1] Based on transplants from 1/1/88 to 4/30/94.
[2] Based on transplants from 1/1/88 to 4/30/92.

## C. NATIONAL GRAFT AND PATIENT SURVIVAL RATES

The national graft and patient survival rates for each organ are displayed in Table II-3. For kidney, liver, and pancreas transplants, patient survival rates are higher than graft survival rates. This may be due to (a) re-transplantation (kidney and liver re-transplantation rates were 13%), (b) returning to dialysis for kidney patients, and (c) insulin administration for pancreas patients. At conditional 3 years post-transplant, graft and patient survival rates are comparable, indicating that re-transplantation, returning to dialysis, and insulin treatment are usually early events following transplantation.

For heart, lung and heart-lung transplants, graft and patient survival rates are comparable at all time points because, for these organ types, graft failure usually leads to patient death.

Conditional 3 year graft and patient survival rates were approximately 90% for all organs, with the exception of lung and heart-lung. Conditional 3 year rates are better than 1 year survival rates for all organ types, indicating that the most critical period of time is the first year post-transplant. Those who survive the first year are very likely to survive 3 years post-transplant.

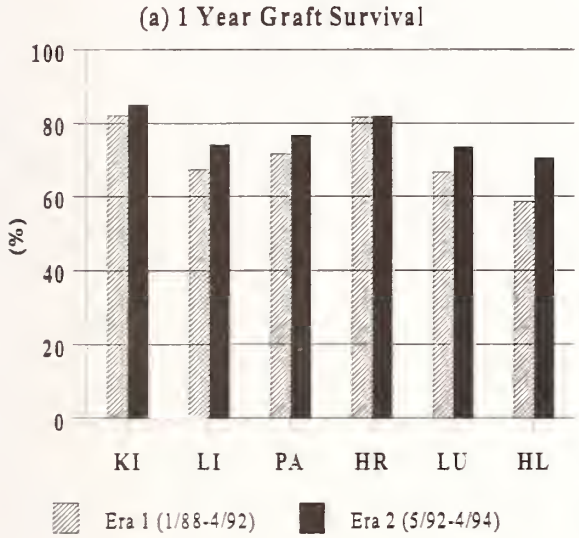
### Survival Rates by Era

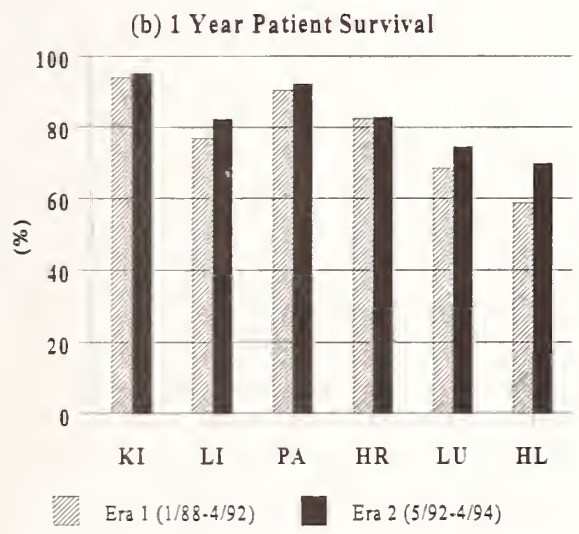
Figure II-1 on the following page presents the 1 year graft and patient survival rates for two different eras -- Era 1, from January 1, 1988, to April 30, 1992; and Era 2, from May 1, 1992, to April 30, 1994. The figure shows a substantial improvement in graft and patient survival rates over time for nearly all organs. The only exception was heart transplants, for which survival rates remained virtually unchanged in the two eras. The greatest changes in survival were seen for heart-lung, lung, and liver with 1 year graft survival rate increases of 12, 7, and 7 percentage points, respectively. These results support the evidence that transplantation outcomes are improving as more effective surgical techniques, medical care, and immunosuppression drugs are developed. Ultimately, patients benefit from these improvements.

**Table II-3. Overall Graft and Patient Survival Rates by Organ**

| Organ | Graft Survival (%) | | | | Patient Survival (%) | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 or 3 Months | 1 Year | 3 Years | Cond. 3 Years | 1 or 3 Months | 1 Year | 3 Years | Cond. 3 Years |
| KI | 88.8 | 83.4 | 75.7 | 90.8 | 97.2 | 94.3 | 89.1 | 94.5 |
| LI | 77.7 | 69.9 | 62.2 | 89.0 | 85.3 | 79.0 | 71.4 | 90.4 |
| PA | 83.6 | 73.5 | 67.1 | 91.3 | 96.1 | 91.1 | 84.1 | 92.3 |
| HR | 91.6 | 81.7 | 73.7 | 90.2 | 92.1 | 82.5 | 74.8 | 90.7 |
| LU | 86.8 | 70.4 | 52.6 | 74.7 | 87.7 | 71.9 | 54.6 | 75.9 |
| HL | 81.9 | 61.9 | 49.6 | 80.1 | 82.2 | 61.9 | 50.3 | 81.2 |

Figure II-1. One Year (a) Graft and (b) Patient Survival Rates by Era




## D. PROGRAMS WITH ACTUAL SURVIVAL RATES SIGNIFICANTLY ABOVE OR BELOW EXPECTED SURVIVAL RATES

After accounting for both donor and recipient characteristics, some transplant programs had either significantly more or fewer patient deaths (graft failures) than were expected statistically. Figure II-2 on the following page illustrates the percentage of programs with actual graft survival rates either significantly below, equal to, or significantly above their expected survival rates, both at 1 year and conditional 3 years. Note that programs with actual survival rates that were *not statistically different* from expected rates are shown in the "equal to" group. The patterns for patient survival rates by program are similar to those shown for graft survival.

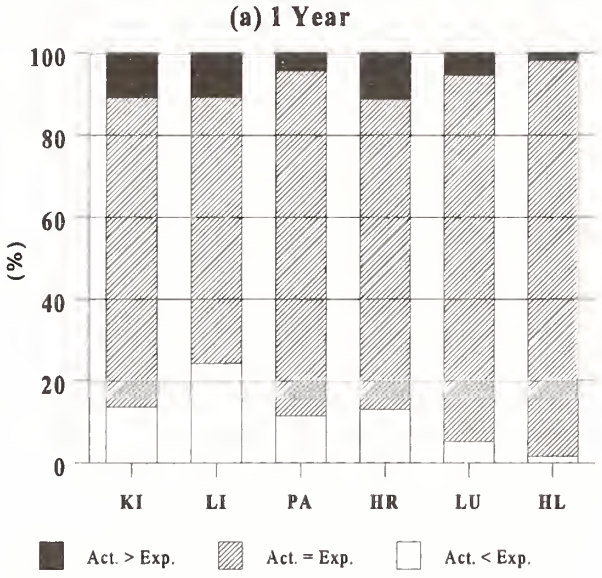
For the majority of transplant programs, the difference in actual and expected graft and patient survival was not statistically significant, regardless of organ type. As depicted in Figure II-2, the "center effects" (i.e., the practices or quality of a transplant program) were most noticeable among liver programs, followed by heart and kidney programs. For example, at 1 year post-transplant, approximately 35% of liver programs had actual survival rates which were significantly different from expected rates. Of these, about 24% of the liver programs had actual survival rates less than expected and 11% of the programs had better than expected survival rates. Fewer significant differences were found among lung and heart-lung programs, probably due to the small number of transplants performed by these programs. The "center effect" diminished considerably for the conditional 3 year survival rates. These data appear to indicate that center effects are most likely to be observed within the first year post-transplant; these effects are less influential on long term survival outcomes. This is supported by the overall conditional 3 year survival rates which were approximately 90% for most organ types and 90% for most of the transplant programs.

### Program Comparisons -- 1994 and 1997 Reports

Compared to the results from the 1994 Report, the 1997 Report had a greater percentage of programs with actual survival rates which were significantly different from their expected rates. In part, this is due to the fact that the number of transplants per

program increased considerably between the 1994 Report and this study. In other words, because of the greater the number of transplants, the power to detect differences between actual and expected survival rates was greater.

**Figure II-2. Percentages of Programs with Actual Graft Survival Rates Above, Below, or Equal to Expected Survival Rates**



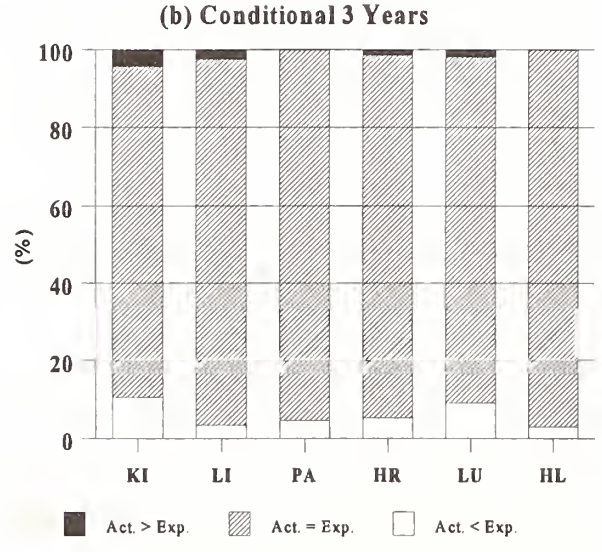




Table II-4 on the following page compares the numbers of (a) kidney, (b) liver, and (c) heart transplant programs with actual 1 year graft survival rates below, equal to, or above their expected survival rates, for the 1994 and 1997 Reports. For example, in the kidney table, 21 programs had less than expected graft survival rates in the 1994 Report. In the 1997 Report, the classification for 15 of these 21 programs remained the same (i.e., their actual survival outcomes were still less than expected) but six programs had actual survival rates which were equal to their expected rates.

There were 13 kidney, 15 liver, and 10 heart programs which began doing transplants after the 1994 Report was produced. Of these new programs, 92% had actual graft survival rates which were equal to or above their expected rates.

The larger differences in actual and expected rates were nearly always seen in programs that reported relatively few transplants during the study period. For example, when looking at 1 year graft survival for kidney, heart, and liver transplant programs, nearly all differences greater than 10% (either above or below expected rates) were found among programs performing fewer than 25 transplants per year (see Figure 2 in each organ specific chapter). Therefore, it is important to consider transplant volume when evaluating the performance of a transplant program.

The UNOS Membership and Professional Standards Committee, in conjunction with UNOS staff, have developed an objective method by which to determine which programs should be investigated due to poor performance. Specifically, the method uses this report to identify potential "poor performance" programs, and then re- evaluates these programs *using more recent data.* Both statistical and clinical significance are important components of this method. Details are described in the Uses of the Report Section of the Overview Chapter.

Table II-4. Numbers of Programs with Actual 1 Year Graft Survival Rates Below (<), Equal to (=), or Above (>) Expected Survival Rates; 1997 and 1994 Reports Compared.

(a) Kidney

| Programs | N | 1997 Report < | = | > |
|---|---|---|---|---|
| 1994 Report | | | | |
| < | 21 | 15 | 6 | 0 |
| = | 193 | 19 | 163 | 11 |
| > | 22 | 0 | 7 | 15 |
| New[1] | 13 | 0 | 12 | 1 |
| Total | 249 | 34 | 188 | 27 |

(b) Liver

| Programs | N | 1997 Report < | = | > |
|---|---|---|---|---|
| 1994 Report | | | | |
| < | 13 | 13 | 0 | 0 |
| = | 68 | 10 | 54 | 4 |
| > | 7 | 0 | 0 | 7 |
| New[1] | 15 | 2 | 13 | 0 |
| Total | 103 | 25 | 67 | 11 |

(c) Heart

| Programs | N | 1997 Report < | = | > |
|---|---|---|---|---|
| 1994 Report | | | | |
| < | 16 | 15 | 1 | 0 |
| = | 123 | 5 | 110 | 8 |
| > | 12 | 0 | 2 | 10 |
| New[1] | 10 | 1 | 9 | 0 |
| Total | 161 | 21 | 122 | 18 |

[1] New programs started after the 1994 Report.

## E. OVERALL DONOR AND RECIPIENT CHARACTERISTICS

*The distribution of all donor and recipient characteristics, overall and by era, can be found in each organ specific chapter. Described below are some of the donor and recipient trends seen when comparing Era 1 (1/88-4/92) and Era 2 (5/92-4/94) data.*

### Donor Trends

The majority of organs transplanted were recovered from white male donors between the ages of 18 and 45. Among cadaveric donors, motor vehicle accidents as a cause of death decreased, while cerebrovascular deaths increased. Donors age 50 and older, minority donors, and living donors all increased between Era 1 and Era 2. (In this report, living donors were included only in the analysis for kidney transplants.)

### Kidney Recipient Trends

Over time, the percentage of minority recipients increased. Simultaneous kidney-pancreas transplants and patients with diabetes or systemic diseases also increased slightly. Recipients with a PRA of 20% or more prior to transplant and those with an HLA mismatch level greater than 3 decreased between Era 1 and Era 2. The incidences of post-transplant delayed graft function and rejection episodes also decreased in Era 2.

### Liver Recipient Trends

More recipients were older with a diagnosis of cirrhosis in Era 2. The percentage of recipients in the intensive care unit (ICU) just prior to transplant decreased substantially. While the re-transplantation rate remained high in both eras, it did decrease slightly over time.

### Pancreas Recipient Trends

Similar to the kidney recipient trends, the percentage of minority recipients increased between Era 1 and Era 2. There was also a slight increase in the number of simultaneous kidney-pancreas transplants.

### Heart Recipient Trends

More recipients were older and in the ICU just prior

to transplant in Era 2 than in Era 1. There also were more minority recipients over time. The number of recipients with cardiomyopathy increased during the study period as did the average length of cold ischemic time.

Lung Recipient Trends

Transplant recipients were older and yet fewer were in the ICU at the time of transplant in the second era. The percentage of recipients with emphysema increased while the percentages of recipients with Alpha-1-Antitrypsin deficiency and primary pulmonary hypertension decreased over time. Also, the mean cold ischemic time increased from Era 1 to Era 2.

Heart-Lung Recipient Trends

In Era 2, the percentage of recipients less than 18 years increased substantially compared to Era 1. The percentage of minority recipients also increased during the second era. Congenital diagnoses, including Eisenmengers syndrome, were the main indication for transplant in Era 2. The mean cold ischemic time increased in the second era also.

## F. CHARACTERISTICS AFFECTING SURVIVAL OUTCOMES

To identify the donor and recipient characteristics affecting graft and patient survival outcomes, separate analyses were performed for each organ and time point of interest. These analyses then were used to calculate each program's expected survival rate. The difference between a program's expected and actual survival rates may provide some indication of the "center effect," or quality of a program.

Of all the donor and recipient characteristics that were initially included in the analyses, some turned out to be exceptionally strong predictors of graft or patient short and long term survival outcomes. Some of the characteristics affecting transplant outcomes for each organ are listed below. Details/further information about the impact of these and other characteristics on short and long term survival can be found in each organ specific chapter.

Kidney

The characteristics with the strongest **positive** impact on **short term** outcomes were:

- Recipient received a living donor transplant
- Recipient was Asian or Hispanic
- Recipient was female
- Year of transplant was 1993 or 1994

The characteristics with the strongest **negative** impact on **short term** outcomes were:

- Recipient received a previous kidney transplant
- Recipient HLA was poorly matched with the donor
- Recipient was in the ICU or hospitalized at the time of transplant
- Recipient was less than 2 years old
- Recipient had diabetes
- Donor was Black or Hispanic

The characteristics with the strongest **positive** impact on **long term** outcomes were:

- Recipient received a living donor transplant
- Recipient was female

The characteristics with the strongest **negative** impact on **long term** outcomes were:

- Recipient received a previous kidney transplant
- Recipient HLA was poorly matched with the donor
- Recipient had diabetes or a systemic disease
- Recipient was Black
- Recipient needed dialysis within the first week post-transplant
- Recipient experienced rejection episodes within 6 months post-transplant
- Donor was Black

Liver

The characteristics with the strongest **positive** impact on **short term** outcomes were:

- Recipient had cholestatic disease/biliary cirrhosis
- Year of transplant was 1993 or 1994

The characteristics with the strongest **negative** impact on **short term** outcomes were:

- Recipient received a previous liver transplant
- Recipient received a reduced or split liver transplant

- Recipient was on life support or in the ICU at the time of transplant
- Recipient's most recent serum creatinine prior to transplant was >2 mg/dl
- Donor was Black or Hispanic
- Donor and recipient blood type were incompatible

The characteristics with the strongest **positive** impact on **long term** outcomes were:

- Recipient was female
- Recipient had acute hepatic necrosis, cholestatic disease/biliary cirrhosis, or a disease from the miscellaneous disease group

The characteristics with the strongest **negative** impact on **long term** outcomes were:

- Recipient received a previous liver transplant
- Recipient received a reduced or split liver transplant
- Recipient was less than 2 years old
- Recipient had malignant neoplasms
- Donor was female

**Pancreas**

The characteristics with the strongest **negative** impact on **short term** outcomes were:

- Recipient received a previous pancreas transplant
- Recipient received a pancreas alone or a pancreas subsequent to a kidney transplant
- Year of transplant was prior to 1991

The characteristics with the strongest **negative** impact on **long term** outcomes were:

- Recipient age was older
- Recipient received a pancreas alone or a pancreas subsequent to a kidney transplant
- Donor was Black
- Donor age was older

**Heart**

The characteristics with the strongest **negative** impact on **short term** outcomes were:

- Recipient received a previous heart transplant
- Recipient had a congenital heart disease
- Recipient was in the ICU and/or on a ventilator/VAD at the time of transplant
- Year of transplant was prior to 1993

The characteristics with the strongest **negative** impact on **long term** outcomes were:

- Recipient received a previous heart transplant
- Recipient was Black or Hispanic
- Donor was Hispanic

**Lung**

The characteristics with the strongest **negative** impact on **short term** outcomes were:

- Recipient received a previous lung transplant
- Transplant type was double lung transplant
- Recipient had fibrosis, primary pulmonary hypertension, or a congenital lung disease
- Recipient was on a ventilator at the time of transplant
- Transplant year was prior to 1993

The characteristics with the strongest **negative** impact on **long term** survival was:

- Recipient race was non-White

**Heart-Lung**

The characteristic with the strongest **negative** impact on **short term** outcomes was:

- Recipient received a previous heart-lung transplant
- Recipient was on a ventilator at the time of transplant
- Year of transplant was prior to 1990

The characteristic with the strongest **negative** impact on **long term** outcomes was:

- Recipient was hospitalized or in ICU at transplant
- Recipient had primary pulmonary hypertension

## G. CONCLUSIONS

The number of transplant programs and transplant procedures performed in the United States continue to grow at a rapid pace. A total of 97,587 transplants for 92,966 recipients performed at 742 transplant programs are included in this report. Since the 1994 Report, the largest increases in the number of

transplant procedures occurred for lung transplants (189% increase), pancreas transplants (88% increase), and liver transplants (73% increase). The number of transplant programs in the 1997 Report is 16% greater than the number of programs in the 1994 Report (640) and 40% greater than those in the 1991 Report (531). *Program growth* between 1991 and 1997 was most notable for lung (213% increase), pancreas (92% increase), and liver (47% increase) programs.

Transplant volume differed greatly among programs. The majority of transplants were performed by a small number of transplant programs. For example, nearly 75% of all liver transplants were performed by only 27% of the 103 liver programs during the period between January 1, 1988 and April 30, 1994. Approximately 20% of the 249 kidney programs performed over 50% of all kidney transplants during the same period. Similarly, about 20% of the 161 heart programs performed over 50% of all heart transplants. Issues relating to transplant program volume may become increasingly important in the future, some studies have already demonstrated a relationship between transplant center volume and outcome.[1,2]

It is encouraging to note that overall graft and patient survival rates have improved for all organs over time (see Figure II-1). For example, the 1 year graft survival rate for lung transplants increased 7 percentage points from Era 1 (1/88-4/92) to Era 2 (5/92-4/94), while the 1 year patient survival rate increased 6 percentage points. The 1 year graft survival rate for heart-lung transplants increased over 12 percentage points, and for lung transplants, it increased over 7 percentage points. Survival rates for liver transplants also increased; at 1 year, graft survival rates increased 7 percentage points and patient survival rates increased 5 percentage points from Era 1 to Era 2. It is unlikely that these observed increases were due entirely to differences in donor and recipient characteristics or to chance alone. Based on the survival analyses performed for each organ, transplants in more recent years were always associated with a statistically significant increase in the odds of survival.

Recipient functional status (i.e., the degree of medical urgency), donor and recipient race, whether the procedure was a first or repeat transplant, and the year of transplant were among the strongest predictors of recipient outcomes. *In general*, characteristics associated with a significantly increased odds of graft failure and/or patient death were (a) being hospitalized just prior to transplant, (b) being a non-White recipient, (c) receiving an organ from a non-White donor, and (d) having a repeat transplant. Heart transplant recipients whose reason for transplant was a congenital disease and liver recipients with a malignancy had poorer outcomes than heart and liver recipients with other diseases.

Despite the statistical adjustment for numerous donor and recipient characteristics, much of the variation in the program specific survival rates remained unexplained by this analysis. Clearly, other factors, some of which may not be easily obtained or quantified, may account for some of the unexplained variation. It also should be noted that in a study of this size, it is possible that statistically significant positive or negative results for some programs may have occurred simply by chance. Nevertheless, in this report, measurable differences in program specific outcomes were determined. The reader is reminded and cautioned that the clinical importance of these differences must be evaluated on a program specific basis.

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1 Hosenpud J.D., Breen T.J., Edwards E.B., et al., 1994. The effect of transplant center volume on cardiac transplant outcome. *JAMA* 271: 1844-1849.

2 Hunsicker L.G., Edwards E.B., Breen T.J. and Daily O.P. 1993. *Transplant Proceedings* 25:1318-1320.

# III. KIDNEY CHAPTER

# III. KIDNEY TRANSPLANT SURVIVAL RATES

*For the Summary of this chapter, see page 42. For definitions of any terms used here, please refer to the User's Guide in the Kidney volume.*

## A. INTRODUCTION

This report of kidney transplant survival rates is based upon verified Scientific Registry data for 62,572 transplants involving 60,340 patients from 249 kidney transplant programs in the United States. Each program reporting at least one kidney or combined kidney-pancreas transplant between January 1, 1988, and April 30, 1994, was included. Multi-organ transplants other than combined kidney-pancreas procedures were excluded.

Short term survival is defined as survival at 3 months and 1 year post-transplant. Short term survival rates are based on all transplants in the study for which there are follow-up data.

Long term survival is defined in two ways:

- unconditional survival at 3 years post-transplant, and
- survival at 3 years post-transplant for those who survived at least 1 year, referred to as **conditional 3 year survival.**

The long term survival rates are based on all transplants between January 1, 1988, and April 30, 1992, for which there are follow-up data. This cohort was chosen to ensure that the maximum number of transplants with follow-up data was used to determine long term survival rates. Please note that the emphasis on long term survival in this report is on the *conditional* 3-year survival rates. This is because the conditional 3-year analysis provides an assessment of characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

## B. COMPLETENESS OF FOLLOW-UP DATA AND OVERALL GRAFT AND PATIENT SURVIVAL RATES

For graft survival, completeness of follow-up data and overall actual survival rates at each time point are shown in Table III-1; patient survival data are shown in Table III-2.

Patient (graft) follow-up data were considered complete when:

- the patient was alive (kidney was functioning) and the duration of survival (function) was equal to or exceeded the specified time after transplant (i.e., 3 months, 1 or 3 years), or
- the patient died (kidney failed) and a valid date of death (failure) was reported.

The percentages of complete follow-up data ranged from a low of 91.7% for the conditional 3 year time point to a high of 99.5% for the 3 month time point.

Overall survival rates also are presented in the tables. Patient survival rates are better than graft survival rates at all time points because patients may survive on dialysis even if their grafts fail. If a graft had incomplete follow-up data, the observation was weighted to account for the time during which the graft was known to be functioning. Therefore, the actual graft survival rate reflects the weighted proportion of grafts functioning at the specified time interval. Patient survival rates were computed in a similar way (see the *Technical Methods* chapter of the *Executive Summary*).

In the calculation of graft survival rates, death with a functioning graft was treated differently depending upon the time interval. For short term survival (3 months, 1 year), grafts were considered to have failed at the time of death because it is reasonable to assume that deaths occurring shortly after a transplant are likely to be related to graft dysfunction. For long term survival, because it is more likely that death might not be related to graft failure, if a patient died with a functioning graft more than 1 year after a transplant, the graft was treated as a censored observation at the time of death. In other words, it was treated as if the graft still functioned but further follow-up data were unavailable. The graft then was weighted for the proportion of time in the period that the graft was functioning (see the *Technical Methods* chapter of the *Executive Summary* for a complete description of weighting.)

In the cohort of transplants (1/1/88 - 4/30/92) used to compute conditional 3 year survival rates, patients (grafts) who did not survive to 1 year after transplant were excluded from the analyses. Therefore, the total number of patients (grafts) for the conditional 3 year analysis was less than that for the 3 month and 1 year analyses. Further, the number of patients is greater than the number of grafts because more grafts failed than patients died within the first year post-transplant.

Please note that the conditional 3 year graft and patient survival rates in Tables III-1 and III-2 may be higher than the 1 year graft survival rates. This is possible because the conditional 3 year survival rates should be interpreted as the 3 year survival rate for patients (grafts) who (which) survived at least 1 year post-transplant.

For example: Program A performed a total of five transplants between 1/1/88 and 4/30/92. Two of the kidneys failed prior to 1 year post-transplant and the remaining three kidneys survived to 3 years after transplant. In this example, Program A has a 1 year graft survival rate of 60% (3 out of 5 kidneys were functioning at 1 year post-transplant). However, the conditional 3 year survival rate for Program A is 100% because all three kidneys that were functioning at 1 year after transplant also were functioning at 3 years post-transplant. The same calculations are used for patient survival. See the *Technical Methods* chapter of the *Executive Summary* for more specific definitions of follow-up data and the calculations for actual graft and patient survival.

**Overall Graft and Patient Survival Rates by Era**

In this report, short term survival also is reported by era. Separate eras were used to determine whether there were any improvements over time in the short term survival rates. Era 1 is defined as all transplants occurring between January 1, 1988, and April 30, 1992; Era 2 includes all transplants occurring between May 1, 1992, and April 30, 1994. The overall graft and patient survival rates by era are presented in the last two columns of Table III-1 and Table III-2, respectively. The results demonstrate improvement in both graft and patient survival rates over time.

**Table III-1. Completeness of Graft Follow-Up Data and Actual Survival Rates for Kidney Transplants**

| Time | Cohort | Number of Transplants | Percent with Follow-Up Data | Graft Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 3 Months | 1/1/88 - 4/30/94 | 62,572 | 99.5 | 88.8 | 87.9 | 90.6 |
| 1 Year | 1/1/88 - 4/30/94 | 62,572 | 98.3 | 83.4 | 82.3 | 85.6 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 33,192 | 91.7 | 90.8* | 90.8* | N/A* |

**Table III-2. Completeness of Patient Follow-Up Data and Actual Survival Rates for Kidney Transplants**

| Time | Cohort | Number of Patients | Percent with Follow-Up Data | Patient Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 3 Months | 1/1/88 - 4/30/94 | 60,340 | 98.9 | 97.2 | 96.9 | 97.6 |
| 1 Year | 1/1/88 - 4/30/94 | 60,340 | 96.5 | 94.3 | 94.0 | 94.9 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 36,394 | 91.9 | 94.5* | 94.5* | N/A* |

* The cohort used to determine the overall conditional 3 year survival rate is the same as the Era 1 cohort. Therefore, the overall conditional 3 year survival rates are identical to the conditional 3 year survival rates for Era 1. There is no conditional 3 year survival rate calculated for Era 2 due to insufficient follow-up data on patients who received transplants in Era 2.

## C. GRAFT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

For each transplant program, actual and expected survival rates were calculated at 3 months, 1 year, and 3 years conditional on survival at 1 year. Survival rates at each time point were determined using a specific cohort of transplants (shown in Tables III-1 and III-2 on the previous page). Expected survival rates were determined for each transplant program based on its specific patient and donor characteristics. These expected outcomes were statistically adjusted for many important prognostic variables, or covariates, that were used in the survival analysis. In other words, they take into account the many different characteristics that affect survival. For example: *if Program A transplanted many more "high risk" recipients than Program B, then Program A would have a lower expected survival rate than Program B.*

If a program's *actual* survival rate was *greater* than its expected survival rate, this means that the program's actual results were higher than the national results for transplants *with the same donor and recipient characteristics.* If a program's *actual* survival rate was *less than* its expected survival rate, this means that the program's actual results were lower than the national results for transplants *with the same donor and recipient characteristics. The difference between the actual and expected rate may have occurred by chance and, therefore, may not be statistically significant.* Furthermore, even a statistically significant difference, one that most likely did not occur by chance, may not be clinically significant (i.e., medically important). A formal description of the methods used to determine actual and expected survival rates appears in the *Technical Methods* chapter of the *Executive Summary.*

Table III-3 shows the percentages of kidney transplant programs by graft survival rates, both for actual and expected survival. The majority of the transplant programs had actual survival rates greater than 80% at all time points. The 1 year survival rates showed a greater variation among programs than the 3 month and conditional 3 year survival rates. At 3 months, 38% of programs had actual survival rates greater than 90%. At 1 year, this fell to 12%. However, the percentage increased to 61% for the conditional 3 year survival rates. The distribution of the expected survival rates shows a similar trend. The results indicate that there are more programs with high survival rates (>90%) at the conditional 3 year time point than there are at the 1 year time point. *This is because the most critical period of time for graft survival is the first year post-transplant.* Those who survive the first year are very likely to survive 3 years post-transplant.

The percentages of programs by short term graft survival rates and eras, both for actual and expected survival, are summarized in Table III-4. The results demonstrate a substantial improvement in graft survival over time because a greater percentage of programs had actual survival rates higher than 90% in Era 2. Expected survival rates in Era 2 also were higher than in Era 1.

**Table III-3. Percentages of Kidney Transplant Programs by Graft Survival Rates**

| Graft Survival Rate (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 3 Months (n= 249) | 1 Year (n=249) | Cond. 3 Yrs (n=236) | 3 Months (n=249) | 1 Year (n=249) | Cond. 3 Yrs (n=236) |
| 0-40 | 0.0 | 0.0 | 0.4 | 0.0 | 0.0 | 0.0 |
| >40-60 | 0.0 | 0.8 | 0.0 | 0.0 | 0.0 | 0.0 |
| >60-80 | 4.8 | 22.9 | 5.5 | 0.0 | 6.0 | 0.0 |
| >80-90 | 57.0 | 63.9 | 33.5 | 71.5 | 92.8 | 31.4 |
| >90-100 | 38.2 | 12.4 | 60.6 | 28.5 | 1.2 | 68.6 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Table III-4. Percentages of Kidney Transplant Programs by Graft Survival Rates and Era**

| Graft Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Era 1 (n=236) | Era 2 (n=240) | Era 1 (n=236) | Era 2 (n=240) | Era 1 (n=236) | Era 2 (n=240) | Era 1 (n=236) | Era 2 (n=240) |
| 0-40 | 0.0 | 0.0 | 0.0 | 0.4 | 0.0 | 0.0 | 0.0 | 0.0 |
| >40-60 | 0.9 | 0.4 | 2.1 | 0.4 | 0.0 | 0.0 | 0.0 | 0.0 |
| >60-80 | 9.3 | 5.0 | 30.5 | 17.1 | 0.0 | 0.0 | 13.6 | 2.9 |
| >80-90 | 54.2 | 36.7 | 55.5 | 56.3 | 86.9 | 27.1 | 86.0 | 92.1 |
| >90-100 | 35.6 | 57.9 | 11.9 | 25.8 | 13.1 | 72.9 | 0.4 | 5.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

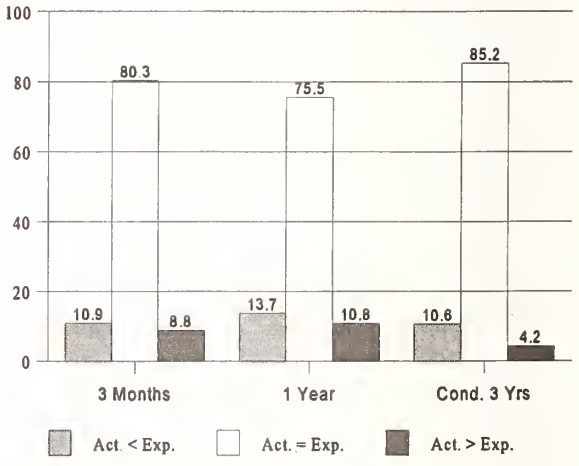
## Differences in Actual and Expected Survival Rates

For most programs, the difference between the actual survival rate and the expected survival rate was not statistically significant. Figure III-1 shows the percentages of programs whose actual graft survival rates were either above, equal to, or below expected graft survival rates at three time points. Programs with actual survival rates that were not significantly different from expected rates are shown in the actual survival equals expected survival group. Actual survival rates shown in the figure to be either greater than or less than expected survival rates were statistically significant. Overall, there were more programs that fell significantly below expected results than above expected results. However, for the majority of the transplant programs, the difference in actual and expected graft survival was not statistically significant and varied little over time.

At all time points, the larger differences in actual and expected rates were nearly always seen in programs that reported relatively few transplants during the period. This occurs because programs that do not perform many transplants tend to have highly variable outcomes. To illustrate this, Figure III-2 shows a scatter plot of the average number of transplants per year (transplant volume) versus the difference in 1 year actual and expected graft survival. Nearly all differences greater than 10% (either positive or negative) are found among transplant programs performing fewer than 25 kidney transplants per year.

Please note that actual survival rates which differ from expected survival rates are not always statistically significant and even statistically significant differences may not be clinically significant.

**Figure III-1. Percentages of Kidney Transplant Programs with Actual Graft Survival Rates Above, Below, or Equal to Expected Rates.***




* Actual survival rates above or below expected survival rates are statistically significant.

## D. PATIENT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

The percentages of programs by patient survival rates for both actual and expected survival are shown in Table III-5; the percentages of programs by survival rates and eras are shown in Table III-6. Note that both actual and expected patient survival rates were higher and less variable at each time point than were actual and expected graft survival rates. As with graft survival, the outcomes in Era 2 were better than in Era 1.

### Differences in Actual and Expected Survival Rates

The percentage of programs with actual patient survival rates significantly above their expected rates was greater at 1 year and conditional 3 years than at 3 months (see Figure III-3). Overall, there were more programs that fell significantly below expected results than above expected results. However, for the majority of transplant programs, the difference in actual and expected patient survival was not statistically significant and varied little over time.

**Figure III-2. Kidney Transplant Volume vs Difference in Actual and Expected 1 Year Graft Survival Rates.**

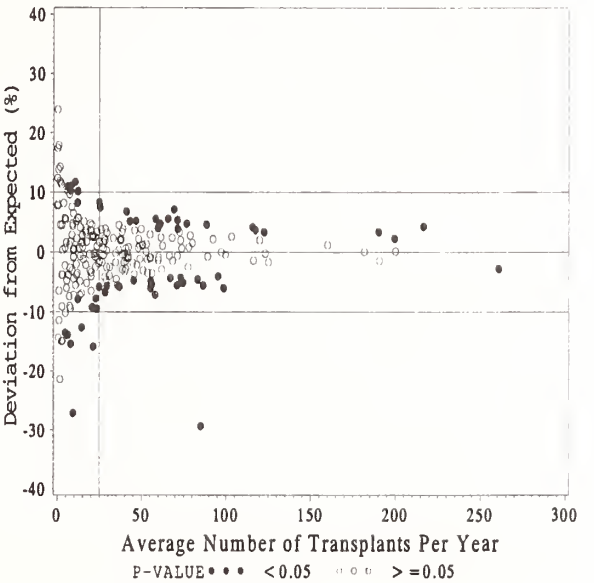


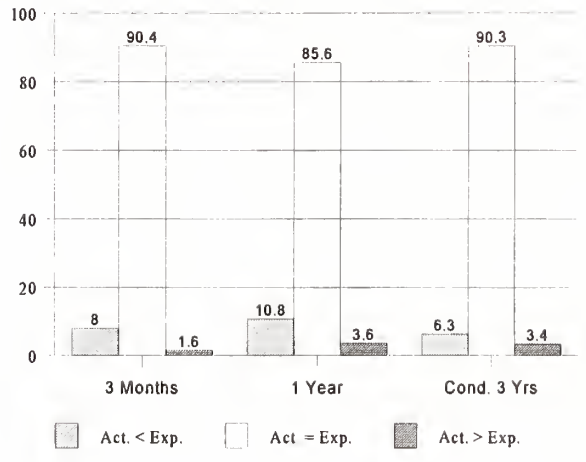

**Table III-5. Percentages of Kidney Transplant Programs by Patient Survival Rates**

| Patient Survival Rate (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 3 Months (n= 249) | 1 Year (n=249) | Cond. 3 Yrs (n=236) | 3 Months (n=249) | 1 Year (n=249) | Cond. 3 Yrs (n=236) |
| 0-70 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| >70-80 | 0.0 | 0.8 | 0.8 | 0.0 | 0.0 | 0.0 |
| >80-90 | 2.4 | 7.6 | 11.5 | 0.4 | 0.8 | 0.4 |
| >90-95 | 9.6 | 50.6 | 43.6 | 0.8 | 67.5 | 64.9 |
| >95-100 | 88.0 | 41.0 | 44.1 | 98.8 | 31.7 | 34.7 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Table III-6. Percentages of Kidney Transplant Programs by Patient Survival Rates and Era**

| Patient Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Era 1 (n=236) | Era 2 (n=240) | Era 1 (n=236) | Era 2 (n=240) | Era 1 (n=236) | Era 2 (n=240) | Era 1 (n=236) | Era 2 (n=240) |
| 0-70 | 0.4 | 0.0 | 0.4 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| >70-80 | 0.0 | 0.4 | 0.8 | 0.8 | 0.0 | 0.0 | 0.0 | 0.0 |
| >80-90 | 2.6 | 2.5 | 11.9 | 10.4 | 0.4 | 0.0 | 0.8 | 0.0 |
| >90-95 | 13.1 | 11.3 | 48.3 | 32.1 | 1.3 | 0.0 | 75.0 | 47.5 |
| >95-100 | 83.9 | 85.8 | 38.6 | 56.7 | 98.3 | 100.0 | 24.2 | 52.5 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Figure III-3. Percentages of Kidney Transplant Programs with Actual Patient Survival Rates Above, Below or Equal to Expected Rates.***




* Actual survival rates above or below expected survival rates are statistically significant.

## E. NATIONAL DISTRIBUTION OF DONOR AND RECIPIENT CHARACTERISTICS

The national distribution of donor and recipient characteristics for kidney transplants, presented in percentages, is shown in Table III-7. Each of these donor and recipient characteristics was included in the analyses for graft or patient survival, and used to determine an expected survival rate for each transplant.

The majority of kidneys transplanted were recovered from white male donors between the ages of 18 and 30 and the most frequent causes of death were cerebrovascular accidents (CVAs) and motor vehicle accidents (MVAs). The most common total HLA mismatch level between donor and recipient was 3 mismatches. Nearly 18% of living donor kidneys had a cold ischemic time of less than two hours. More than 35% of cadaveric kidney donors had a cold ischemic time of less than 22 hours.

The majority of kidney recipients were white males between the ages of 18 and 35. Most recipients were not hospitalized prior to transplant, and nearly 65% of the recipients showed some level of sensitization (peak PRA > 0) at the time of transplant. Of the 62,572 transplants, 13% were repeat kidney transplants. In addition, 21% (=9.1%+11.6%) of the recipients required dialysis within first week after transplant, and 41% (=21.7%+19.6%) had rejection episodes within the first 6 months following transplant.

### Donor Trends

National donor characteristics changed between Era 1 and Era 2. The percentage of living donors increased 3.5%. Among cadaveric donors, there were fewer donors who died from motor vehicle accidents and more who died from cerebrovascular accidents. The

percentage of donors over age 45 increased by nearly 5% between Era 1 and Era 2, from 20.5% to 25% . The percentage of minority donors also increased, from 19% to 23%. The percentage of zero antigen mismatched kidney donors also increased slightly, which could be due to the national policy of mandatory sharing of well matched kidney during that period.

## Recipient Trends

Transplant recipients were older in the second era; those over age 45 comprised 38% of recipients in Era 2 as compared to 33% in Era 1. Simultaneous kidney-pancreas transplants also increased slightly. Recipients with peak PRAs under 20% increased from 73% in Era 1 to 79% in Era 2. The percentage of transplants for patients with some type of glomerular disease decreased while transplants for patients with systemic and diabetic diseases increased slightly. The incidence of delayed graft function post surgery (requiring dialysis within first week after transplant) decreased by 3% between Era 1 and Era 2, from 22% (=13.9%+7.7%) to 19.1%. Also, the incidence of rejection episodes within six months following transplant dropped from 43% (=33%+10%) to 38%.

Despite more older donors and older recipients in Era 2, the national survival rates improved from Era 1 to Era 2 (See Tables III-1 and III-2).

**Table III-7. National Donor and Recipient Characteristics in Kidney Transplants: Percentages by Era and Overall.**

| Characteristics by Category | | ERA 1 1/88-4/92 N=41126 | ERA 2 5/92-4/94 N=21446 | OVERALL 1/88-4/94 N=62572 |
|---|---|---|---|---|
| Donor Type and Donor Cause of Death | Living | 22.0 | 25.5 | 23.2 |
| | Cadaveric: CVA | 24.3 | 26.3 | 25.0 |
| | Cadaveric: MVA | 23.2 | 17.6 | 21.3 |
| | Cadaveric: Other | 30.4 | 30.4 | 30.4 |
| | Not Reported | 0.1 | 0.2 | 0.1 |
| Donor Age | 0-17 | 17.6 | 16.3 | 17.2 |
| | 18-30 | 32.4 | 28.6 | 31.1 |
| | 31-45 | 29.4 | 30.0 | 29.6 |
| | 46-60 | 17.3 | 19.9 | 18.2 |
| | 61+ | 3.2 | 5.1 | 3.8 |
| | Not Reported | 0.0 | 0.1 | 0.1 |
| Donor Race | White | 80.8 | 76.5 | 79.4 |
| | Black | 9.5 | 11.9 | 10.3 |
| | Hispanic | 7.4 | 8.9 | 7.9 |
| | Asian | 1.2 | 1.5 | 1.3 |
| | Other | 1.0 | 1.0 | 1.0 |
| | Not Reported | 0.1 | 0.2 | 0.1 |

| | | ERA 1 | ERA 2 | OVERALL |
|---|---|---|---|---|
| **Donor Gender** | Female | 40.8 | 42.1 | 41.2 |
| | Male | 59.2 | 57.9 | 58.8 |
| | Not Reported | 0.0 | 0.0 | 0.0 |
| **Cold Ischemic Time (Hours) by Donor Type** | Living: 0-2 | 17.9 | 16.8 | 17.5 |
| | Living: 3-5 | 0.8 | 1.4 | 1.0 |
| | Living: 6+ | 0.6 | 1.4 | 0.9 |
| | Cadaveric: 0-11 | 9.3 | 9.6 | 9.4 |
| | Cadaveric: 12-21 | 25.3 | 26.6 | 25.8 |
| | Cadaveric: 22-31 | 24.0 | 20.7 | 22.8 |
| | Cadaveric: 32-41 | 13.6 | 9.7 | 12.3 |
| | Cadaveric: 42+ | 4.7 | 2.8 | 4.0 |
| | Not Reported | 3.8 | 11.0 | 6.3 |
| **Level of HLA Mismatch** | 0 | 8.9 | 10.6 | 9.5 |
| | 1 | 5.4 | 5.9 | 5.6 |
| | 2 | 15.1 | 16.1 | 15.4 |
| | 3 | 25.3 | 26.1 | 25.6 |
| | 4 | 22.8 | 21.6 | 22.4 |
| | 5 | 15.0 | 13.1 | 14.3 |
| | 6 | 5.0 | 4.4 | 4.8 |
| | Not Reported | 2.5 | 2.4 | 2.4 |
| **Recipient Age** | 0-17 | 6.7 | 5.6 | 6.3 |
| | 18-35 | 33.7 | 30.5 | 32.6 |
| | 36-45 | 26.4 | 25.9 | 26.2 |
| | 46-60 | 26.6 | 29.0 | 27.4 |
| | 61+ | 6.6 | 9.0 | 7.4 |
| | Not Reported | 0.0 | 0.0 | 0.0 |
| **Recipient Race** | White | 66.4 | 64.7 | 65.9 |
| | Black | 20.0 | 20.8 | 20.3 |
| | Hispanic | 8.7 | 9.6 | 9.0 |
| | Asian | 2.6 | 3.2 | 2.8 |
| | Other | 2.2 | 1.5 | 2.0 |
| | Not Reported | 0.1 | 0.2 | 0.1 |
| **Recipient Gender** | Female | 39.9 | 40.4 | 40.1 |
| | Male | 60.1 | 59.6 | 59.9 |
| | Not Reported | 0.0 | 0.0 | 0.0 |

| | | ERA 1 | ERA 2 | OVERALL |
|---|---|---|---|---|
| **Procedure Type** | Kidney Alone | 96.2 | 94.3 | 95.5 |
| | Kidney and Pancreas | 3.8 | 5.7 | 4.5 |
| **Previous Kidney Transplant** | No | 85.8 | 87.9 | 86.5 |
| | Yes | 13.9 | 11.8 | 13.2 |
| | Not Reported | 0.3 | 0.3 | 0.3 |
| **Pretransplant Transfusions** | 0 | 35.3 | 24.1 | 31.4 |
| | 1-5 | 38.5 | 34.4 | 37.1 |
| | 6-10 | 11.0 | 5.7 | 9.2 |
| | 11+ | 10.8 | 3.9 | 8.4 |
| | Not Reported | 4.5 | 31.9 | 13.9 |
| **Peak PRA Prior to Transplant** | 0 | 30.8 | 36.3 | 32.7 |
| | 1-19 | 42.6 | 42.5 | 42.6 |
| | 20-79 | 17.1 | 13.6 | 15.9 |
| | 80-100 | 7.5 | 5.5 | 6.8 |
| | Not Reported | 1.8 | 2.1 | 1.9 |
| **Body Mass Index ($kg/m^2$)** | 0-20 | 20.5 | 15.4 | 18.7 |
| | 21-25 | 40.7 | 33.0 | 38.1 |
| | 26-30 | 20.4 | 18.9 | 19.9 |
| | 31+ | 8.8 | 10.0 | 9.2 |
| | Not Reported | 9.6 | 22.7 | 14.1 |
| **Primary Kidney Disease** | Glomerular | 28.3 | 24.7 | 27.0 |
| | Cystic/Congenital | 12.0 | 11.2 | 11.7 |
| | Systemic | 18.4 | 19.6 | 18.8 |
| | Tubulointerstitial | 7.2 | 6.0 | 6.8 |
| | Diabetes | 22.0 | 23.3 | 22.5 |
| | Other Diagnosis | 7.8 | 9.5 | 8.4 |
| | Not Reported | 4.3 | 5.7 | 4.8 |
| **Recipient Description at Transplant** | Not Hospitalized | 94.2 | 95.8 | 94.7 |
| | Hospitalized | 3.6 | 2.0 | 3.1 |
| | ICU/Life Support | 1.0 | 0.2 | 0.7 |
| | Not Reported | 1.2 | 2.0 | 1.4 |

| | | ERA 1 | ERA 2 | OVERALL |
|---|---|---|---|---|
| **Year of Transplant** | 1988 | 21.9 | 0.0 | 14.4 |
| | 1989 | 21.8 | 0.0 | 14.3 |
| | 1990 | 23.9 | 0.0 | 15.7 |
| | 1991 | 24.5 | 0.0 | 16.1 |
| | 1992 | 7.9 | 32.2 | 16.2 |
| | 1993-1994 | 0.0 | 67.8 | 23.2 |
| **Dialysis in First Week After Transplant*** | Yes | 13.9 | 0.0 | 9.1 |
| | No | 64.5 | 0.0 | 42.4 |
| | Not Reported | 2.3 | 0.0 | 1.5 |
| | N.A.*: Yes | 7.7 | 19.1 | 11.6 |
| | N.A.*: No | 10.7 | 79.7 | 34.4 |
| | N.A.*: Not Reported | 0.9 | 1.2 | 1.0 |
| **Rejection in First 6 Months After Transplant*** | Yes | 33.0 | 0.0 | 21.7 |
| | No | 47.7 | 0.0 | 31.4 |
| | N.A.*: Yes | 10.0 | 38.0 | 19.6 |
| | N.A.*: No | 9.3 | 62.0 | 27.3 |

* The data shown for dialysis and rejection, used to model the conditional 3 year survival outcomes, were based on all transplants from 1/88 through 4/94. Note that the numbers in the N.A. categories were not used in the conditional analysis due to either graft failure or a transplant after 4/92.

## F. SHORT TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

To determine the expected survival for each transplant or patient, separate analyses were performed for graft and patient survival at three time points. (The analyses were performed using logistic regression, see the *Technical Methods* chapter in the *Executive Summary.*) The analyses also identified donor and recipient characteristics that had a significant impact on survival outcomes. For each *characteristic* (e.g., race, gender) considered in the analyses, a *reference group* was chosen (e.g., White, male) with which the other groups were compared. As a general rule, the largest group or the mean of the characteristic (e.g., mean recipient age=40) is often used as the reference group.

The following served as the characteristics and reference groups for ***short term graft*** survival:

- Donor Type -- cadaveric donors
- Donor Cause of Death -- cerebral vascular accident (CVA)
- Mean Donor Age -- 32 years
- Donor Race -- non-Black, non-Hispanic
- Donor Gender -- male
- Mean Cold Ischemic Time -- 23 hours (cadaveric donors), 1 hour (living donors)
- HLA Mismatch Level -- zero
- Previous kidney transplant -- no
- Mean Recipient Age -- 40 years
- Recipient Race -- White

**Table III-8. Kidney Primary Disease Diagnoses at Time of Transplant**

| | |
|---|---|
| **Diabetes**<br><br>Type I Insulin Dependent<br>Type II Insulin Dependent<br>Type I Non-Insulin Dependent<br>Type II Non-Insulin Dependent | **Cystic/Congenital Diseases (CC)**<br><br>Cystinosis<br>Polycystic Kidneys<br>Oxalosis<br>Fabry's Disease<br>Hypoplasia<br>Medullary Cystic Disease<br>Alport's Syndrome<br>Prune Belly Syndrome |
| **Glomerular Diseases (GN)**<br><br>Idiopathic and post-infectious crescentic glomerulonephritis<br>Membranous glomerulonephritis<br>Mesangio-capillary (Type 1) glomerulonephritis<br>Mesangio-capillary (Type 2) glomerulonephritis<br>IgA nephropathy<br>Anti-GBM<br>Focal glomerulosclerosis<br>Goodpasture's Syndrome<br>Chronic Glomerulonephritis -- unspecified<br>Membranous Nephropathy | **Systemic Diseases (SD)**<br><br>Amyloidosis<br>Systemic lupus erythematosus<br>Progressive Systemic Sclerosis<br>Wilms' tumor<br>Renal Cell Carcinoma<br>Incidental Carcinoma<br>Myeloma<br>Hemolytic Uremic Syndrome<br>Cortical Necrosis<br>Acute Tubular Necrosis<br>Sickle Cell Anemia<br>Familial Nephropathy<br>Malignant Hypertension<br>Henoch-Schonlein Purpura<br>Hypertensive Nephrosclerosis (kidney disease caused by hypertension)<br>Renal Artery Thrombosis<br>Chronic Nephrosclerosis -- unspecified<br>Scleroderma<br>Wegener's Granulomatosis<br>Polyarteritis<br>Rheumatoid Arthritis<br>Sarcoidosis<br>Lymphoma |
| **Tubulointerstitial Diseases (TI)**<br><br>Chronic Pyelonephritis (Reflux Nephropathy)<br>Interstitial Nephritis<br>Gout<br>Obstructive Uropathy<br>Analgesic Nephropathy<br>Radiation Nephritis<br>Antibiotic - induced nephritis<br>Cancer -- Chemotherapy induced nephritis<br>Cyclosporin Nephrotoxicity<br>Heroin Nephrotoxicity<br>Congenital Obstructive Uropathy<br>Nephrolithiasis | |

- Recipient Gender -- male
- Transplant Procedure Type -- kidney alone
- Primary Kidney Disease -- recipient had non-diabetes, non-systemic (SD), and non-tubulointerstitial (TI) diseases at transplant (see Table III-8 for a complete list of primary disease diagnoses)
- Mean Body Mass Index -- 24 $kg/m^2$
- Mean Peak PRA -- 16%
- Pre-transplant Transfusions -- none
- Medical Status -- not hospitalized prior to transplant
- Year of Transplant -- 1988

The following served as the characteristics and reference groups for ***short term patient*** survival:

- Donor Type -- cadaveric donors
- Donor Cause of Death -- cerebral vascular accident (CVA)
- Mean Donor Age -- 32 years
- Donor Race -- non-Black
- Donor Gender -- male
- Mean Cold Ischemic Time -- 23 hours (cadaveric donors), 1 hour (living donors)
- HLA Mismatch Level -- zero
- Previous kidney transplant -- no
- Mean Recipient Age -- 40 years
- Recipient Race -- non-Black or non-Hispanic
- Recipient Gender -- male
- Transplant Procedure Type -- kidney alone
- Primary Kidney Disease -- recipient had either glomerular (GM) or tubulointerstitial (TI) disease at transplant (see Table III-8 for complete list of primary disease diagnoses)
- Mean Body Mass Index -- 24
- Mean Peak PRA -- 16%
- Pre-transplant Transfusions -- none
- Medical Status -- not hospitalized prior to transplant
- Year of Transplant -- 1988

The relative impact of each donor and recipient characteristic on short term graft and patient survival outcomes is listed in Table III-9. For each characteristic, the ***odds ratio*** is the odds of patient death (graft failure) as compared to the reference group, after adjusting for the effects of all other donor and recipient characteristics. An *odds ratio of less than 1* indicates that the characteristic was associated with a *reduced odds* of patient death or graft failure relative to the reference group. An odds ratio of *greater than 1* indicates that the characteristic was associated with an *increased odds* of death relative to the reference group. The corresponding p-value measures the significance of the odds ratio. A p-value less than 0.05 indicates statistical significance and means that there is less than a 5% probability that such difference is due to chance alone. The smaller the p-value, the greater the statistical significance and the less likely the difference is due to chance alone.

**Examples**

In Table III-9, the odds ratio of graft failure within 3 months after a repeat transplant versus a first, or primary, transplant was 1.43. This means that, after adjusting for all of the other donor and recipient characteristics, the odds of graft failure within 3 months was 43% greater for repeat transplants than for primary transplants ((1.43-1)×100%=43%). As another example, the odds ratio of graft failure within 3 months post-transplant for a recipient who was in the intensive care unit (ICU) or on life support prior to transplant versus a recipient who was not hospitalized was 2.16. After adjusting for the effects of both donor and recipient characteristics, the odds of graft failure within 3 months for a patient who was in the ICU or on life support prior to transplant was 116% higher ((2.16-1)×100%=116%) than that for a patient who was not hospitalized prior to transplant.

The estimated odds ratios for continuous variables (i.e., variables with many possible values) such as cold ischemic time, donor and recipient ages, peak PRA, and body mass indices are less easily interpreted. For these variables, the estimated odds is determined for every 5 or 10 unit increase or decrease from the mean (reference group) of the variable. For example, in Table III-9, the estimated odds of 3 month graft failure for 33 hours of cold ischemic time compared to the mean of 23 hours is 1.07. This means that, after adjusting for the effects of all other characteristics, the odds of graft failure was estimated to increase by 7% for the first 10 hour increase from the mean cold ischemic time.

An increase of 25 hours from the mean (i.e., the cold ischemic time is 23+25=48) would result in an 18% increase in the odds of graft failure. Mathematically, this 18% was calculated as follows:

$$\text{Odds ratio} = \exp^{\left(\frac{25}{10}\times 0.0661\right)} = 1.18$$

**Table III-9. Impact of Donor and Recipient Characteristics on Short Term Graft and Patient Survival--Kidney Transplants**

| Short Term Characteristics | Graft Survival [1] | | | | Patient Survival [1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Odds Ratio | P-value [2] | Odds Ratio | P-value [2] | Odds Ratio | P-value [2] | Odds Ratio | P-value [2] |
| Living vs Cadaveric Donor | 0.482 | <0.001 | 0.476 | <0.001 | 0.508 | <0.001 | 0.568 | <0.001 |
| Donor Cause of Death MVA vs CVA | 0.770 | <0.001 | 0.804 | <0.001 | --- | n.d. | --- | n.d. |
| Donor Cause of Death Other vs CVA | 0.830 | <0.001 | 0.854 | <0.001 | --- | n.d. | --- | n.d. |
| Donor Age 42 vs 32 [3] | 1.066 | <0.001 | 1.096 | <0.001 | 1.067 | <0.001 | 1.090 | <0.001 |
| Donor Black vs White, Asian, Other | 1.267 | <0.001 | 1.303 | <0.001 | --- | n.d. | --- | n.d. |
| Donor Hispanic vs White, Asian, and Other | 1.187 | <0.001 | 1.128 | <0.001 | --- | n.d. | --- | n.d. |
| Donor Black vs Non-Black | --- | n.d. | --- | n.d. | 1.243 | 0.008 | 1.340 | <0.001 |
| Donor Female vs Male | 1.131 | <0.001 | 1.154 | <0.001 | --- | n.d. | --- | n.d. |
| Cold Ischemic Time (hours) 33 vs 23 for Cadaveric Donors, 11 vs 1 for Living Donors [3] | 1.068 | <0.001 | 1.062 | <0.001 | --- | n.d. | --- | n.d. |
| 1 vs 0 HLA Mismatch | 1.599 | <0.001 | 1.563 | <0.001 | 1.373 | 0.035 | 1.264 | 0.031 |
| 2 vs 0 HLA Mismatches | 1.589 | <0.001 | 1.630 | <0.001 | 1.212 | 0.124 | 1.236 | 0.016 |
| 3 vs 0 HLA Mismatches | 1.856 | <0.001 | 1.786 | <0.001 | 1.318 | 0.017 | 1.247 | 0.007 |
| 4 vs 0 HLA Mismatches | 2.081 | <0.001 | 2.040 | <0.001 | 1.342 | 0.013 | 1.359 | <0.001 |
| 5 vs 0 HLA Mismatches | 2.293 | <0.001 | 2.206 | <0.001 | 1.459 | 0.002 | 1.425 | <0.001 |
| 6 vs 0 HLA Mismatches | 2.561 | <0.001 | 2.360 | <0.001 | 1.421 | 0.019 | 1.440 | <0.001 |
| Previous Transplant -- Yes vs No | 1.426 | <0.001 | 1.334 | <0.001 | 1.300 | 0.001 | 1.232 | <0.001 |
| Recipient Age 50 vs 40 [3] | 1.024 | 0.028 | 1.058 | <0.001 | 1.437 | <0.001 | 1.452 | <0.001 |
| Recipient Age <2 vs Age ≥ 2 | 1.924 | <0.001 | 1.728 | <0.001 | 5.404 | <0.001 | 6.492 | <0.001 |
| Recipient Black vs White | 0.966 | 0.327 | 1.097 | 0.002 | --- | n.d. | --- | n.d. |
| Recipient Hispanic vs White | 0.702 | <0.001 | 0.763 | <0.001 | --- | n.d. | --- | n.d. |
| Recipient Asian vs White | 0.711 | <0.001 | 0.745 | <0.001 | --- | n.d. | --- | n.d. |
| Recipient Other Race vs White | 0.743 | 0.003 | 0.785 | <0.001 | --- | n.d. | --- | n.d. |
| Recipient Black vs White, Asian, & Other | --- | n.d. | --- | n.d. | 0.905 | 0.144 | 0.876 | 0.008 |
| Recipient Hispanic vs White, Asian, & Other | --- | n.d. | --- | n.d. | 0.649 | <0.001 | 0.710 | <0.001 |
| Recipient Female vs Male | --- | n.d. | --- | n.d. | 0.875 | 0.012 | 0.882 | 0.001 |
| Kidney-Pancreas vs Kidney Alone | 0.810 | 0.005 | 0.989 | 0.867 | 1.436 | 0.002 | 1.468 | <0.001 |

| Short Term Characteristics | Graft Survival [1] | | | | Patient Survival [1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Odds Ratio | P-value [2] | Odds Ratio | P-value [2] | Odds Ratio | P-value [2] | Odds Ratio | P-value [2] |
| Diabetes vs GM [4], CC [4], & Other [4] | 1.213 | <0.001 | 1.231 | <0.001 | --- | n.d. | --- | n.d. |
| SD [4] vs GM, CC, & Other | 1.050 | 0.185 | 1.066 | 0.039 | --- | n.d. | --- | n.d. |
| TI [4] vs GM, CC, & Other | 0.880 | 0.024 | 0.890 | 0.015 | --- | n.d. | --- | n.d. |
| Diabetes vs GM and TI | --- | n.d. | --- | n.d. | 1.734 | <0.001 | 1.866 | <0.001 |
| CC vs GM and TI | --- | n.d. | --- | n.d. | 0.784 | 0.010 | 0.883 | 0.065 |
| SD vs GM and TI | --- | n.d. | --- | n.d. | 1.120 | 0.136 | 1.170 | 0.005 |
| Other vs GM and TI | --- | n.d. | --- | n.d. | 1.091 | 0.319 | 1.205 | 0.003 |
| Body Mass Index 29 vs 24 [3] | 1.101 | <0.001 | 1.097 | <0.001 | 1.072 | 0.012 | 1.011 | 0.563 |
| Peak PRA 26% vs 16% [3] | 1.080 | <0.001 | 1.072 | <0.001 | 1.030 | 0.125 | 1.025 | 0.079 |
| Pre-transplant Transfusions--Yes vs No | 0.881 | <0.001 | 0.904 | <0.001 | --- | n.d. | --- | n.d. |
| Hospitalized vs Not Hospitalized | 1.133 | 0.065 | 1.166 | <0.001 | 1.121 | 0.389 | 1.233 | 0.026 |
| In ICU/on Life Support vs Not Hospitalized | 2.162 | <0.001 | 2.293 | <0.001 | 4.021 | <0.001 | 2.820 | <0.001 |
| TX Year 1989 vs 1988 | 0.861 | <0.001 | 0.838 | <0.001 | 0.875 | 0.107 | 0.881 | 0.041 |
| TX Year 1990 vs 1988 | 0.809 | <0.001 | 0.802 | <0.001 | 0.838 | 0.033 | 0.859 | 0.014 |
| TX Year 1991 vs 1988 | 0.629 | <0.001 | 0.608 | <0.001 | 0.554 | <0.001 | 0.608 | <0.001 |
| TX Year 1992 vs 1988 | 0.611 | <0.001 | 0.615 | <0.001 | 0.670 | <0.001 | 0.712 | <0.001 |
| TX Year 1993-1994 vs 1988 | 0.614 | <0.001 | 0.615 | <0.001 | 0.537 | <0.001 | 0.623 | <0.001 |

Notes:

[1] In the short term survival analysis, if a patient died with a functioning graft (DWFG), the kidney was considered to have failed at the time of death.

[2] n.d. denotes p-value not determined due to either (a) using a different reference group, or (b) results not statistically significant, and therefore factor is not included in the analysis.

[3] Odds ratios for continuous covariates (donor age, cold ischemic time, recipient age, peak PRA, and body mass index) do not have a linear relationship. The odds ratios presented in this table correspond to 5 or 10 unit increases from the mean of each covariate. The mean donor age was 32. The mean cold ischemic times for living and cadaveric donors were 1 and 23 hours, respectively. The mean recipient age was 40, the mean peak PRA was 16%, and the mean body mass index was 24.

[4] Glomerular Diseases (GM), Tubulointerstitial Diseases (TI), Cystic, Congenital, Hereditary Diseases (CC), Systemic Diseases (SD), Other disease diagnoses.

where the 25 hour increase is equivalent to 2.5 per 10 hour difference, and 0.0661 corresponds to the coefficient of cold ischemic time per 10 hour difference (see Table III-12 for coefficients). Therefore, the increase in the odds of graft failure is (1.18-1)×100%=18%. For some variables such as recipient age and recipient body mass index, it is necessary to add a quadratic term. For more details on calculating odds ratios for continuous variables, refer to the section on *Odds Ratios* in the *Technical Methods* chapter of the *Executive Summary*.

Graft Survival

The donor characteristics with the strongest impact on short term graft survival were donor type, donor cause of death, donor race, and level of HLA mismatch between the donor and the recipient. The odds of 1 year graft failure was 52% lower in transplants from living donors than in those from cadaveric donors, and 30% higher in transplants from Black donors than those from non-Black and non-Hispanic donors. The odds of graft failure for 4 to 6 antigen mismatch transplants was more than twice that for zero antigen mismatch transplants.

The recipient characteristics that had the strongest impact on short term graft survival were whether recipient had any previous kidney transplant, recipient under age 2, race, disease diagnosis at transplant, pre-transplant transfusions, medical condition at transplant, and year of transplant. The 3 month odds ratio of graft failure for a recipient under 2 years of age was almost twice that of recipients age 2 and older. Repeat transplants had a 43% greater odds of failing within 3 months than did first transplants. Hispanic and Asian recipients had a 30% lower odds of graft failure at 3 months post-transplant than did White recipients. Transplants performed during 1993 and the first four months of 1994 had an almost 40% reduced odds of failure compared to transplants performed in 1988.

Patient Survival

As seen with graft survival, the donor characteristics with the strongest impact on short term patient survival were donor type, donor race, and HLA mismatch level. The odds of mortality for living donor transplant recipients was nearly half that for cadaveric donor transplant recipients. The odds of mortality for recipients of Black donor kidneys was greater than that for recipients of non-Black donors. Recipients of poorly matched kidneys (6 antigen mismatch) had approximately a 40% increased odds of mortality relative to recipients of well matched kidneys (zero antigen mismatch). However, HLA antigen mismatch levels overall had less impact on patient survival than on graft survival. Donor cause of death, donor gender, and cold ischemic time had no significant effect on patient survival. In this analysis, Asian and "other" (not Black, White, Hispanic, or Asian) races were grouped with White as the reference group because these factors did not have a statistically significant impact on patient survival.

Recipient age younger than 2 years, previous transplant, disease diagnosis at transplant, medical condition at transplant, and year of transplant were found to influence strongly patient mortality. When compared to those of other ages, recipients under 2 years old had the greatest odds of short term mortality. Specifically, compared to the odds of patient death among recipients age 2 and older, the odds of patient death among recipients under 2 was 5.40 times greater at 3 months post-transplant and 6.49 times greater at 1 year post-transplant. Also at an increased odds of mortality were recipients of repeat transplants, whose odds of death was 30% greater at 3 months than that for recipients of primary transplants. The odds of death within 3 months after transplant for recipients in the ICU or on life support at transplant was more than four times that of recipients who were not hospitalized just prior to transplant. This increased odds of death dropped to 2.82 for these recipients at 1 year post-transplant. Recipients of transplants in 1992, 1993, and 1994 had a 29% to 38% reduction in the odds of death at 1 year post-transplant relative to recipients of transplants in 1988. This finding is consistent with the improved kidney patient survival rates over time. Having a pre-transplant transfusion was significant for short term graft survival but had no significant effect on short term patient survival.

## G. LONG TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

In this report, long term survival analyses were developed separately from the short term survival analyses. Because this narrative focuses on conditional 3 year survival (survival at 3 years for grafts or patients surviving at least 1 year post-transplant), only conditional 3 year survival data are presented in this text. Both conditional and

unconditional 3 year survival rates are provided in the tables for each transplant program presented in each organ specific volume.

The conditional 3 year survival analyses provide an assessment of the donor and recipient characteristics that are independent of those limited to the first year (e.g., surgical complications). Furthermore, for the long term survival analysis, if a patient died with a functioning graft, the graft was not considered to have failed as it was with short term survival. *This was done because deaths occurring some years after a transplant are less likely to be related to the transplant.*

The impact of each donor and recipient characteristic on graft and patient long term survival is listed in Table III-10. Notice that two models were used for graft and patient survival rates. Model II includes two post-transplant covariates not found in Model I:

1. Delayed graft function--defined as the need for dialysis in the first week after transplant.
2. Rejection--defined as whether a patient experienced rejection episodes in the first six months following transplant.

Using the post-transplant covariates found in Model II allows for an assessment of the effects of early post-transplant events (e.g., onset of acute tubular necrosis and early rejections) on long term survival. However, while these two covariates may be related to long term survival outcomes, they also may be highly related to practices at individual transplant programs. Therefore, in assessing the quality of a program (i.e., the "center effect"), each program's expected survival rates were calculated based on Model I, the model without these two covariates.

The following characteristics and reference groups were used for ***long term graft*** survival:

- Donor Type -- cadaveric donors
- Donor Cause of Death -- non-Motor Vehicle Accident (MVA)
- Mean Donor Age -- 32 years
- Donor Race -- non-Black
- Donor Gender -- male
- Mean Cold Ischemic Time -- 23 hours (cadaveric donors), 1 hour (living donors)
- HLA Mismatch Level -- zero
- Previous kidney transplant -- no
- Mean Recipient Age -- 40 years
- Recipient Race -- non-Black or non-Hispanic
- Recipient Gender -- male
- Transplant Procedure Type -- kidney alone
- Primary Disease Diagnosis -- non-systemic (SD), non-cystic/congenital (CC), or non-tubulointerstitial (TI) disease at transplant (see Table III-8 for a complete list of primary disease diagnoses)
- Mean Body Mass Index -- 24 $kg/m^2$
- Mean Peak PRA -- 16%
- Pre-transplant Transfusions -- none
- Medical Status -- not in ICU or on life support prior to transplant
- Year of Transplant -- 1988

The following characteristics and reference groups were used for ***long term patient*** survival:

- Donor Type -- cadaveric donors
- Donor Cause of Death -- non-Motor Vehicle Accident (MVA)
- Mean Donor Age -- 32 years
- Donor Race -- non-Black
- Donor Gender -- male
- Mean Cold Ischemic Time -- 23 hours (cadaveric donors), 1 hour (living donors)
- HLA Mismatch Level -- zero
- Previous kidney transplant -- no
- Mean Recipient Age -- 40 years
- Recipient Race -- non-Hispanic
- Recipient Gender -- male
- Transplant Procedure Type -- kidney alone
- Primary Disease Diagnosis -- recipient had glomerular (GM) or cystic/congenital (CC) or tubulointerstitial (TI) disease at transplant (see Table III-8 for a complete list of primary disease diagnoses)
- Mean Body Mass Index -- 24 $kg/m^2$
- Mean Peak PRA -- 16%
- Pre-transplant Transfusions -- none
- Medical Status -- not in ICU or on life support prior to transplant
- Year of Transplant -- 1988
- Delayed Graft Function -- no
- Rejection Episodes -- no

Table III-10. Impact of Donor and Recipient Characteristics on Long Term Graft and Patient Survival -- Kidney Transplants

| Long Term Characteristics | Graft [1] | | | | Patient [1] | | | |
|---|---|---|---|---|---|---|---|---|
| | Model I [2] | | Model II [2] | | Model I [2] | | Model II [2] | |
| | Odds Ratio | P-value [3] | Odds Ratio | P-value [3] | Odds Ratio | P-value [3] | Odds Ratio | P-value [3] |
| Living vs Cadaveric Donor | 0.531 | <0.001 | 0.563 | <0.001 | 0.612 | <0.001 | 0.667 | <0.001 |
| Donor Cause of Death MVA vs Other | 0.897 | 0.034 | 0.901 | 0.044 | --- | n.d. | --- | n.d. |
| Donor Age 42 vs 32 [4] | 1.158 | <0.001 | 1.143 | <0.001 | 1.082 | <0.001 | 1.064 | <0.001 |
| Donor Black vs Non-Black | 1.183 | 0.009 | 1.180 | 0.010 | 1.231 | 0.009 | 1.217 | 0.014 |
| Donor Female vs Male | --- | n.d. | --- | n.d. | 1.242 | <0.001 | 1.236 | <0.001 |
| Cold Ischemic Time (hours) 33 vs 23 for Cadaveric Donors, 11 vs 1 for Living Donors [4] | --- | n.d. | --- | n.d. | --- | n.d. | --- | n.d. |
| 1 vs 0 HLA Mismatch | 1.557 | <0.001 | 1.525 | 0.001 | 1.467 | 0.009 | 1.439 | 0.013 |
| 2 vs 0 HLA Mismatches | 1.700 | <0.001 | 1.617 | <0.001 | 1.434 | 0.003 | 1.380 | 0.008 |
| 3 vs 0 HLA Mismatches | 1.744 | <0.001 | 1.648 | <0.001 | 1.448 | 0.001 | 1.374 | 0.005 |
| 4 vs 0 HLA Mismatches | 1.853 | <0.001 | 1.749 | <0.001 | 1.472 | <0.001 | 1.392 | 0.005 |
| 5 vs 0 HLA Mismatches | 1.733 | <0.001 | 1.595 | <0.001 | 1.520 | <0.001 | 1.426 | 0.003 |
| 6 vs 0 HLA Mismatches | 1.990 | <0.001 | 1.826 | <0.001 | 1.799 | <0.001 | 1.674 | <0.001 |
| Previous Transplant -- Yes vs No | 1.132 | 0.037 | 1.106 | 0.094 | 1.193 | 0.022 | 1.157 | 0.061 |
| Recipient Age 50 vs 40 [4] | 0.772 | <0.001 | 0.782 | <0.001 | 1.440 | <0.001 | 1.455 | <0.001 |
| Recipient Age <2 vs Age ≥2 | --- | n.d. | --- | n.d. | --- | n.d. | --- | n.d. |
| Recipient Black vs White, Asian & Other | 2.232 | <0.001 | 2.209 | <0.001 | --- | n.d. | --- | n.d. |
| Recipient Hispanic vs White, Asian & Other | 1.215 | 0.006 | 1.244 | 0.002 | --- | n.d. | --- | n.d. |
| Recipient Hispanic vs non-Hispanic | --- | n.d. | --- | n.d. | 0.761 | 0.005 | 0.770 | 0.007 |
| Recipient Female vs Male | --- | n.d. | --- | n.d. | 0.808 | <0.001 | 0.814 | <0.001 |
| Kidney-Pancreas vs Kidney Alone | 0.756 | 0.021 | 0.715 | 0.006 | --- | n.d. | --- | n.d. |
| CC [5] vs GM [5], Diabetes and Other [5] | 0.695 | <0.001 | 0.699 | <0.001 | --- | n.d. | --- | n.d. |
| SD [5] vs GM, Diabetes and Other | 1.260 | <0.001 | 1.274 | <0.001 | --- | n.d. | --- | n.d. |
| TI [5] vs GM, Diabetes and Other | 0.837 | 0.032 | 0.842 | 0.040 | --- | n.d. | --- | n.d. |
| Diabetes vs GM, CC and TI | --- | n.d. | --- | n.d. | 2.775 | <0.001 | 2.787 | <0.001 |
| SD vs GM, CC and TI | --- | n.d. | --- | n.d. | 1.504 | <0.001 | 1.500 | <0.001 |
| Other vs GM, CC and TI | --- | n.d. | --- | n.d. | 1.304 | 0.002 | 1.317 | 0.001 |
| Body Mass Index 29 vs 24 [4] | 1.097 | <0.001 | 1.090 | <0.001 | 0.937 | 0.013 | 0.925 | 0.003 |

| Long Term Characteristics | Graft [1] | | | | Patient [1] | | | |
|---|---|---|---|---|---|---|---|---|
| | Model I [2] | | Model II [2] | | Model I [2] | | Model II [2] | |
| | Odds Ratio | P-value [3] | Odds Ratio | P-value [3] | Odds Ratio | P-value [3] | Odds Ratio | P-value [3] |
| **Peak PRA 26% vs 16% [4]** | 1.019 | 0.012 | 1.014 | 0.064 | 1.049 | <0.001 | 1.040 | <0.001 |
| **Pre-transplant Transfusions--Yes vs No** | --- | n.d. | --- | n.d. | --- | n.d. | --- | n.d. |
| **Medical Condition at Transplant** | --- | n.d. | --- | n.d. | --- | n.d. | --- | n.d. |
| **TX Year 1989 vs 1988** | 0.907 | 0.087 | 0.904 | 0.078 | 0.848 | 0.016 | 0.850 | 0.018 |
| **TX Year 1990 vs 1988** | 0.786 | <0.001 | 0.787 | <0.001 | 0.749 | <0.001 | 0.735 | <0.001 |
| **TX Year 1991- 1992 vs 1988** | 0.646 | <0.001 | 0.659 | <0.001 | 0.723 | <0.001 | 0.741 | <0.001 |
| **Dialysis within 1st Week After TX** | --- | n.d. | 1.206 | <0.001 | --- | n.d. | 1.427 | <0.001 |
| **Rejection within 6 months After TX** | --- | n.d. | 1.488 | <0.001 | --- | n.d. | 1.288 | <0.001 |

Notes:

[1] In the long term survival analysis, if a patient died with a functioning graft (DWFG), the kidney was not considered to have failed at the time of death.

[2] Model I does not include the two post-transplant covariates (the last two items in the table); Model II does include them.

[3] n.d. denotes p-value not determined due to either (a) using a different reference group, or (b) results not statistically significant, and therefore factor is not included in the analysis.

[4] Odds ratio for continuous covariates (donor age, cold ischemic time, recipient age, peak PRA, and body mass index) do not have a linear relationship. The odds ratios presented in this table correspond to 5 or 10 unit increases from the mean of each covariate. The mean donor age was 32. The means cold ischemic time for living and cadaveric donors were 1 and 23 hours, respectively. The mean recipient age was 40, the mean peak PRA was 16%, and the mean body mass index was 24.

[5] Glomerular Diseases (GM), Tubulointerstitial Diseases (TI), Cystic, Congenital Diseases (CC), Systemic Diseases (SD), Other Disease Diagnosis.

## Graft Survival

The results using Models I and II, without and with the two post-transplant covariates, respectively, were very similar (see Table III-10). In Model I, the donor characteristics with the strongest impact on long term graft survival were donor type (living or cadaveric), donor race, and HLA mismatch level. Based on the conditional 3 year analysis, the odds of graft failure was at least 47% lower in living donor transplants than in cadaveric donor transplants ((.531-1) ×100%=-47%); and 18% higher in Black donor transplants than in non-Black donor transplants. HLA mismatch level still played an important role in long term survival. The odds of graft failure for 6 antigen mismatch transplants was nearly twice that of zero antigen mismatch transplants. Donor gender and cold ischemic time had no significant effect on graft survival and were not included in the analysis.

The recipient characteristics that had the strongest impact on graft survival were age, race, transplant procedure type (kidney-pancreas or kidney alone), diagnosis at transplant, and year of transplant. Black recipients had an approximately 120% greater odds of graft failure than did non-Black and non-Hispanic recipients. Recipients of a simultaneous kidney-pancreas had a 24% lower odds of graft failure than did recipients of a kidney alone. When compared to the glomerular (GM), diabetes, and "other" disease

groups, the systemic disease (SD) group had the highest odds of graft failure. Patients who had cystic, congenital (CC), or tubulointerstitial (TI) diseases, however, had a 16% to 30% lower odds of graft failure. Finally, in Model II, the results demonstrated that delayed graft function (i.e., requiring dialysis within the first week post-transplant) and rejection episodes within 6 months post-transplant had a significant impact on long term survival outcomes, with the odds of graft failure increased by 20% for recipients requiring dialysis, and 49% for recipients having rejection episodes after transplant.

Patient Survival

As was seen with graft survival, the donor characteristics with the strongest impact on patient survival were donor type (living or cadaveric), donor race, and HLA mismatch level. Unlike the graft survival analysis, donor gender had a strong impact on patient survival. The Model I analysis shows that living donor transplants had a 39% lower odds of patient mortality than did cadaveric transplants. The odds of mortality for recipients of kidneys from Black donors was about 23% greater than that for recipients of kidneys from non-Black donors. Recipients of poorly matched kidneys (6 antigen mismatch) had an approximately 80% increased odds of mortality relative to recipients of well matched kidneys (zero antigen mismatch). Overall, the various HLA antigen mismatch levels had less impact on patient survival than on graft survival. As with graft survival, cold ischemic time had no significant effect on patient survival and was not included in the analysis.

Black recipients had worse long term graft survival but similar patient survival as compared to White and Asian recipients. Although Hispanic recipients had a higher chance of graft failure relative to White, Asian, and "Other" races, they had lower patient mortality. Recipient gender was found to affect patient mortality -- the odds of death was 19% lower for women than for men. Though transplant procedure type (simultaneous kidney-pancreas or pancreas alone), pre-transplant transfusions, and medical condition were important predictors of short term patient survival, they were not statistically significant in the long term analysis. Disease diagnosis and the year of transplant were found to be important predictors of long term patient mortality. In particular, diabetes had a nearly 180% higher odds of patient mortality than the reference group of glomerular (GM), cystic/congenital (CC), and tubulointerstitial (TI) disease groups. The systemic disease (SD) group had a 50% increased odds of patient mortality compared to the reference group. The "other" disease group (i.e., non-diabetes, non-SD, non-GM, non-CC, and non-TI ) also showed an increased odds of mortality. Diabetes, SD, and "other" disease groups had a greater negative impact on patient survival than on graft survival. In general, recipients of transplants in more recent years had a decreased odds of mortality.

## H. COMPARISON BETWEEN SHORT TERM AND LONG TERM CHARACTERISTICS

The majority of the donor and recipient characteristics that had a strong impact on short term graft survival appeared to have a strong impact on long term graft survival as well. Some exceptions were donor and recipient gender, recipient age less than 2 years, cold ischemic time, pre-transplant transfusions, and medical condition prior to transplant. Donor cause of death was significant for short and long term graft survival but not for short or long term patient survival. Donor gender did not have a significant impact on short term patient survival but was significant in the long term. The impact of some characteristics (e.g., cold ischemic time, pre-transplant transfusions) simply diminished over time.

Medical condition at the time of transplant was significant for short term graft and patient survival but was not significant for long term survival. In addition, the effect of recipient age less than 2 years was highly significant in the short term analysis but not significant in the long term analysis. However, for recipients who were less than 2 years old or who were in critical condition prior to transplant, the risk of graft failure or mortality was usually so high that the patients did not survive long enough (i.e., at least 1 year), to be included in the conditional 3 year analysis. This might explain why these two factors were not significant in the long term analysis.

For some characteristics, their negative effect on graft survival increased over time. For instance, the odds of graft failure at 3 months for Black recipients compared to White recipients was 0.97, then increased to 1.10 at 1 year, and was 2.23 in the conditional 3 years analysis. Similarly, the odds of failure at 3 months for Hispanic recipients compared to White recipients was 0.70, which increased to 0.76

at 1 year, and 1.22 in the conditional 3 years analysis. In the short term, patients who had systemic diseases (SD) showed a marginal difference in the odds of graft failure compared to patients with glomerular diseases (GM). In the long term, patients with SD had a 50% increased odds of graft failure compared to patients with GM, CC, or TI diseases.

## I. STATISTICAL METHODS AND MODELS

***This section provides a brief summary of the statistical methods used to determine survival rates for kidney transplants, both nationally and at each transplant program. It is not necessary to read this section in order to utilize the rest of the report. For additional statistical details, please see the Technical Methods chapter in the Executive Summary.***

### Model Significance -- $R^2$

The conclusion that there is a "center effect" in kidney transplantation often is based on the observation that actual survival rates vary considerably among kidney transplant programs. However, in reality, only part of the variability can be attributed to the quality of the program (the so called "center effect"); the rest can be attributed to the differences in donor and recipient characteristics among transplant programs. The degree to which the variability in actual survival rates can be attributed to the specific donor and recipient characteristics in each analysis appears in Table III-11.

**Table III-11. Kidney Model $R^2$: Comparison of the 1994 and 1997 Reports**

| Outcome | Time Point | Report Year | Number of Covariates | $R^2$ |
|---|---|---|---|---|
| **Graft Model $R^2$** | 3 Months | 1997<br>1994 | 37<br>31 | 19.1<br>17.6 |
| | 1 Year | 1997<br>1994 | 37<br>31 | 22.4<br>25.1 |
| | Cond. 3 Years * | 1997<br>1994 | 24<br>N.A. | 29.1<br>N.A. |
| **Patient Model $R^2$** | 3 Months | 1997<br>1994 | 34<br>29 | 3.7<br>6.3 |
| | 1 Year | 1997<br>1994 | 34<br>29 | 3.9<br>5.6 |
| | Cond. 3 Years * | 1997<br>1994 | 25<br>N.A. | 23.9<br>N.A. |

* Conditional 3 year analysis was not performed in the 1994 report.

In the table, the values in the column labeled $R^2$ estimate the percentage of variability in the actual survival rates that can be attributed to the covariates in each analysis. *The higher the percentage, the better the analysis explained the individual program outcomes, based on the characteristics examined.* Theoretically, if an analysis contained every covariate that affected survival outcomes, and there were no differences in quality among programs (i.e., no "center effect"), then $R^2$ would equal 100%. In practice, we can never capture every factor that affects outcomes, and it is likely that real differences among programs do exist. This means that any unexplained variation can probably be attributed to a combination of true center effect and covariates not considered in this study. (For details on the $R^2$ calculation, refer to the *Model Significance* section in the *Technical Methods* chapter of the *Executive Summary*. )

The value of $R^2$ estimated from analyses in the 1994 Report was compared to the value of the $R^2$ analyses in the 1997 Report. Note that these analyses are not *directly* comparable since each was used with a different cohort of transplants. Nevertheless, the extensive characteristics considered in the 1997 Report appear to explain similar amount of the variability in the actual survival rates. Despite the refinements in the 1997 Report, as compared to the 1994 Report, much of the variation in actual survival rates among the 249 transplant programs in the study remains unexplained by the analyses. This suggests that much of the risk involved in transplantation is due to characteristics not described in this report.

## Estimated Coefficients and Standard Errors from the Logistic Regression Models

Tables III-12 and III-13 list the coefficients and the standard errors of the coefficients at each time point for all of the donor and recipient characteristics used in the logistic regression models. Each coefficient is reported on the logistic scale and represents the $\log_e$ odds of graft failure or the $\log_e$ odds of patient mortality for the corresponding characteristic at the specified time after transplant. The adjusted odds ratio on the probability scale may be obtained by applying the exponential function to the coefficient. For further details, see the *Odds Ratios* section in the *Technical Methods* chapter of the *Executive Summary*.

## Expected Kidney Transplant Survival Rates

Table III-14 shows the 1 year *expected graft* survival rates for kidney transplants and kidney-pancreas transplants for a given set of donor and recipient characteristics; Table III-15 shows the 1 year *expected patient* survival rates. These rates were determined using the following characteristics: recipient age, disease diagnosis, type of donor, and primary or repeat transplant. For these analyses, all other characteristics were set to the values for the reference groups, with the exception of the year of transplant (1993-1994), and the HLA mismatch level (3). The complete list of reference groups is shown on page 24.

For example, in Table III-14, the expected 1 year *graft* survival rate for a 65 year old diabetic recipient of a primary cadaveric kidney transplant was almost the same as that for a diabetic kidney-pancreas recipient of the same age (81.1% vs 81.3%). In contrast, the expected 1 year *patient* survival rates for a diabetic kidney recipient was nearly 6% higher than that for a diabetic kidney-pancreas recipient (85.3% vs 79.8%).

**Table III-12. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Short Term Kidney Transplant Survival**

| Short Term Characteristics [2] | Graft Survival [1] | | | | Patient Survival [1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| Intercept | -2.485 | 0.077 | -2.090 | 0.065 | -3.881 | 0.136 | -3.276 | 0.098 |
| Living vs Cadaveric Donor | -0.729 | 0.047 | -0.743 | 0.040 | -0.677 | 0.090 | -0.565 | 0.062 |
| Donor Cause of Death MVA vs CVA | -0.261 | 0.042 | -0.219 | 0.036 | --- | --- | --- | --- |
| Donor Cause of Death Other vs CVA | -0.186 | 0.037 | -0.158 | 0.032 | --- | --- | --- | --- |
| Donor Age -Linear (per 10 years) [3,4] | 0.007 | 0.010 | 0.029 | 0.008 | 0.048 | 0.016 | 0.057 | 0.012 |
| -Quadratic (per 10 years) [3,4] | 0.057 | 0.004 | 0.063 | 0.004 | 0.017 | 0.009 | 0.029 | 0.006 |
| Donor Black vs White, Asian, Other | 0.237 | 0.043 | 0.265 | 0.037 | --- | --- | --- | --- |
| Donor Hispanic vs White, Asian, and Other | 0.172 | 0.052 | 0.121 | 0.045 | --- | --- | --- | --- |
| Donor Black vs Non-Black | --- | --- | --- | --- | 0.217 | 0.082 | 0.293 | 0.059 |
| Donor Female vs Male | 0.123 | 0.028 | 0.143 | 0.024 | --- | --- | --- | --- |
| Cold Ischemic Time (per 10 hours) [4] | 0.066 | 0.013 | 0.063 | 0.011 | --- | --- | --- | --- |
| 1 vs 0 HLA Mismatch | 0.470 | 0.082 | 0.447 | 0.070 | 0.317 | 0.150 | 0.234 | 0.108 |
| 2 vs 0 HLA Mismatches | 0.463 | 0.068 | 0.488 | 0.057 | 0.192 | 0.125 | 0.211 | 0.088 |
| 3 vs 0 HLA Mismatches | 0.618 | 0.064 | 0.580 | 0.053 | 0.276 | 0.116 | 0.221 | 0.082 |
| 4 vs 0 HLA Mismatches | 0.733 | 0.065 | 0.713 | 0.055 | 0.295 | 0.118 | 0.307 | 0.084 |
| 5 vs 0 HLA Mismatches | 0.830 | 0.067 | 0.791 | 0.057 | 0.378 | 0.123 | 0.354 | 0.087 |
| 6 vs 0 HLA Mismatches | 0.941 | 0.079 | 0.859 | 0.068 | 0.351 | 0.149 | 0.365 | 0.106 |
| Previous Transplant -- Yes vs No | 0.355 | 0.037 | 0.288 | 0.033 | 0.262 | 0.081 | 0.209 | 0.060 |
| Recipient Age - Linear (per 10 years) [3,4] | -0.019 | 0.010 | 0.006 | 0.008 | 0.298 | 0.022 | 0.318 | 0.016 |
| - Quadratic (per 10 years) [3,4] | 0.043 | 0.005 | 0.050 | 0.005 | 0.065 | 0.011 | 0.057 | 0.008 |
| Recipient Age <2 vs Age ≥ 2 | 0.654 | 0.191 | 0.547 | 0.176 | 1.687 | 0.372 | 1.871 | 0.254 |
| Recipient Black vs White | -0.034 | 0.035 | 0.093 | 0.030 | --- | --- | --- | --- |
| Recipient Hispanic vs White | -0.355 | 0.053 | -0.270 | 0.045 | --- | --- | --- | --- |
| Recipient Asian vs White | -0.342 | 0.089 | -0.294 | 0.075 | --- | --- | --- | --- |
| Recipient Other Race vs White | -0.297 | 0.099 | -0.242 | 0.086 | --- | --- | --- | --- |
| Recipient Black vs White, Asian, & Other | --- | --- | --- | --- | -0.100 | 0.068 | -0.133 | 0.050 |
| Recipient Hispanic vs White, Asian & Other | --- | --- | --- | --- | -0.432 | 0.107 | -0.342 | 0.075 |
| Recipient Female vs Male | --- | --- | --- | --- | -0.134 | 0.053 | -0.125 | 0.038 |
| Kidney-Pancreas vs Kidney Alone | -0.210 | 0.074 | -0.011 | 0.060 | 0.362 | 0.114 | 0.384 | 0.081 |

| Short Term Characteristics [2] | Graft Survival [1] | | | | Patient Survival [1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| Diabetes vs GM [5], CC [5], & Other [5] | 0.193 | 0.035 | 0.208 | 0.030 | --- | --- | --- | --- |
| SD [5] vs GM, CC, & Other | 0.049 | 0.036 | 0.064 | 0.031 | --- | --- | --- | --- |
| TI [5] vs GM, CC, & Other | -0.128 | 0.056 | -0.116 | 0.048 | --- | --- | --- | --- |
| Diabetes vs GM and TI | --- | --- | --- | --- | 0.551 | 0.070 | 0.624 | 0.051 |
| CC vs GM and TI | --- | --- | --- | --- | -0.244 | 0.095 | -0.124 | 0.067 |
| SD vs GM and TI | --- | --- | --- | --- | 0.113 | 0.076 | 0.157 | 0.056 |
| Other vs GM and TI | --- | --- | --- | --- | 0.087 | 0.088 | 0.187 | 0.063 |
| Body Mass Index - Linear (per 5 kg/m$^2$) [3,4] | 0.096 | 0.014 | 0.092 | 0.012 | 0.047 | 0.034 | -0.030 | 0.024 |
| -Quadratic(per 5 kg/m$^2$) [3,4] | --- | --- | --- | --- | 0.022 | 0.013 | 0.042 | 0.009 |
| Peak PRA - Linear (per 10%) [3,4] | 0.077 | 0.005 | 0.069 | 0.004 | 0.025 | 0.022 | 0.020 | 0.016 |
| - Quadratic (per 10%) [3,4] | --- | --- | --- | --- | 0.004 | 0.004 | 0.004 | 0.003 |
| Pre-transplant Transfusions--Yes vs No | -0.128 | 0.027 | -0.101 | 0.023 | --- | --- | --- | --- |
| Hospitalized vs Not Hospitalized | 0.125 | 0.068 | 0.154 | 0.059 | 0.115 | 0.133 | 0.209 | 0.094 |
| In ICU/on Life Support vs Not Hospitalized | 0.771 | 0.113 | 0.830 | 0.102 | 1.391 | 0.158 | 1.037 | 0.137 |
| TX Year 1989 vs 1988 | -0.150 | 0.044 | -0.176 | 0.038 | -0.134 | 0.083 | -0.127 | 0.062 |
| TX Year 1990 vs 1988 | -0.212 | 0.044 | -0.220 | 0.038 | -0.177 | 0.083 | -0.152 | 0.062 |
| TX Year 1991 vs 1988 | -0.464 | 0.046 | -0.497 | 0.040 | -0.591 | 0.092 | -0.498 | 0.066 |
| TX Year 1992 vs 1988 | -0.493 | 0.047 | -0.486 | 0.040 | -0.400 | 0.087 | -0.340 | 0.064 |
| TX Year 1993-1994 vs 1988 | -0.488 | 0.044 | -0.485 | 0.037 | -0.622 | 0.084 | -0.472 | 0.060 |

Notes:

[1] In the short term survival analysis, if a patient died with a functioning graft (DWFG), the kidney was considered to have failed at the time of death.

[2] Not all characteristics were included in the graft and patient analyses. This is denoted by "---" due to either (a) using a different reference group, or (b) results not statistically significant.

[3] In the analysis, the continuous covariates (donor age, cold ischemic time, recipient age, peak PRA, and body mass index) were centered at their mean. The mean donor age was 32. The mean cold ischemic times for living and cadaveric donors were 1 and 23 hours, respectively. The mean recipient age was 40, the mean peak PRA was 16%, and the mean body mass index was 24.

[4] Modeling the continuous covariates with a linear and a quadratic term (the square of the linear term) is necessary due to the relationship between the covariate and the odds of graft failure or patient death.

[5] Glomerular Diseases (GM), Tubulointerstitial Diseases (TI), Cystic, Congenital Diseases (CC), Systemic Diseases (SD), Other Disease Diagnosis.

**Table III-13. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Long Term Kidney Transplant Survival**

| Long Term Characteristics [3] | Graft [1] | | | | Patient [1] | | | |
|---|---|---|---|---|---|---|---|---|
| | Model I [2] | | Model II [2] | | Model I [2] | | Model II [2] | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| Intercept | -2.888 | 0.107 | -3.059 | 0.108 | -3.612 | 0.127 | -3.782 | 0.129 |
| Living vs Cadaveric Donor | -0.633 | 0.064 | -0.574 | 0.065 | -0.491 | 0.080 | -0.405 | 0.081 |
| Donor Cause of Death MVA vs Other | -0.109 | 0.052 | -0.105 | 0.052 | --- | --- | --- | --- |
| Donor Age - Linear (per 10 years) [4,5] | 0.092 | 0.014 | 0.083 | 0.014 | 0.048 | 0.016 | 0.035 | 0.016 |
| -Quadratic (per 10 years) [4,5] | 0.054 | 0.007 | 0.051 | 0.007 | 0.031 | 0.009 | 0.027 | 0.009 |
| Donor Black vs Non-Black | 0.168 | 0.065 | 0.166 | 0.065 | 0.208 | 0.080 | 0.197 | 0.080 |
| Donor Female vs Male | --- | --- | --- | --- | 0.217 | 0.049 | 0.217 | 0.049 |
| Cold Ischemic Time (per 10 hours) [4] | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 vs 0 HLA Mismatch | 0.443 | 0.128 | 0.422 | 0.128 | 0.383 | 0.146 | 0.364 | 0.146 |
| 2 vs 0 HLA Mismatches | 0.531 | 0.105 | 0.480 | 0.105 | 0.360 | 0.121 | 0.322 | 0.121 |
| 3 vs 0 HLA Mismatches | 0.556 | 0.100 | 0.499 | 0.100 | 0.370 | 0.114 | 0.318 | 0.114 |
| 4 vs 0 HLA Mismatches | 0.617 | 0.103 | 0.559 | 0.103 | 0.387 | 0.116 | 0.331 | 0.116 |
| 5 vs 0 HLA Mismatches | 0.550 | 0.107 | 0.467 | 0.108 | 0.419 | 0.121 | 0.355 | 0.121 |
| 6 vs 0 HLA Mismatches | 0.688 | 0.126 | 0.602 | 0.126 | 0.587 | 0.141 | 0.515 | 0.142 |
| Previous Transplant -- Yes vs No | 0.124 | 0.060 | 0.101 | 0.060 | 0.176 | 0.077 | 0.146 | 0.078 |
| Recipient Age - Linear (per 10 years) [4,5] | -0.259 | 0.016 | -0.247 | 0.016 | 0.335 | 0.021 | 0.346 | 0.021 |
| - Quadratic (per 10 years) [4,5] | --- | --- | --- | --- | 0.030 | 0.011 | 0.029 | 0.011 |
| Recipient Age <2 vs Age ≥2 | --- | --- | --- | --- | --- | --- | --- | --- |
| Recipient Black vs White, Asian & Other | 0.803 | 0.049 | 0.793 | 0.049 | --- | --- | --- | --- |
| Recipient Hispanic vs White, Asian & Other | 0.195 | 0.071 | 0.218 | 0.071 | --- | --- | --- | --- |
| Recipient Hispanic vs non-Hispanic | --- | --- | --- | --- | -0.273 | 0.097 | -0.261 | 0.097 |
| Recipient Female vs Male | --- | --- | --- | --- | -0.213 | 0.051 | -0.206 | 0.051 |
| Kidney-Pancreas vs Kidney Alone | -0.280 | 0.121 | -0.335 | 0.122 | --- | --- | --- | --- |
| CC [6] vs GM [6], Diabetes and Other [6] | -0.364 | 0.074 | -0.358 | 0.074 | --- | --- | --- | --- |
| SD [6] vs GM, Diabetes and Other | 0.231 | 0.050 | 0.242 | 0.050 | --- | --- | --- | --- |
| TI [6] vs GM, Diabetes and Other | -0.179 | 0.083 | -0.172 | 0.083 | --- | --- | --- | --- |
| Diabetes vs GM, CC and TI | --- | --- | --- | --- | 1.021 | 0.059 | 1.025 | 0.059 |
| SD vs GM, CC and TI | --- | --- | --- | --- | 0.408 | 0.067 | 0.405 | 0.067 |

| Long Term Characteristics [3] | Graft [1] | | | | Patient [1] | | | |
|---|---|---|---|---|---|---|---|---|
| | Model I [2] | | Model II [2] | | Model I [2] | | Model II [2] | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| **Other vs GM, CC and TI** | --- | --- | --- | --- | 0.265 | 0.086 | 0.275 | 0.086 |
| **Body Mass Index -Linear (per 5 kg/m$^2$) [4,5]** | 0.093 | 0.021 | 0.086 | 0.021 | -0.119 | 0.031 | -0.134 | 0.031 |
| **-Quadratic(per 5 kg/m$^2$) [4,5]** | --- | --- | --- | --- | 0.054 | 0.012 | 0.057 | 0.012 |
| **Peak PRA - Linear (per 10%) [4]** | 0.019 | 0.008 | 0.014 | 0.008 | 0.048 | 0.009 | 0.039 | 0.009 |
| **Pre-transplant Transfusions--Yes vs No** | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medical Condition at Transplant** | --- | --- | --- | --- | --- | --- | --- | --- |
| **TX Year 1989 vs 1988** | -0.098 | 0.057 | -0.101 | 0.057 | -0.165 | 0.069 | -0.162 | 0.069 |
| **TX Year 1990 vs 1988** | -0.241 | 0.058 | -0.240 | 0.058 | -0.289 | 0.069 | -0.283 | 0.069 |
| **TX Year 1991- 1992 vs 1988** | -0.437 | 0.055 | -0.417 | 0.056 | -0.325 | 0.065 | -0.300 | 0.065 |
| **Dialysis within 1st Week After TX** | --- | --- | 0.187 | 0.049 | --- | --- | 0.356 | 0.055 |
| **Rejection within 6 months After TX** | --- | --- | 0.398 | 0.041 | --- | --- | 0.253 | 0.049 |

Notes:

[1] In the long term survival analysis, if a patient died with a functioning graft (DWFG), the kidney was considered to be lost to follow-up at the time of death.

[2] Model I is forced *not* to include the post-transplant covariates (the last two items in the above table). Model II is forced to include them.

[3] Not all characteristics were included in the graft and patient analyses. This is denoted by "---" due to either (a) using a different reference group, or (b) results not statistically significant.

[4] In the analysis, the continuous covariates (donor age, cold ischemic time, recipient age, peak PRA, and body mass index) were centered at their mean. The mean donor age was 32. The mean cold ischemic times for living and cadaveric donors were 1 and 23 hours, respectively. The mean recipient age was 40, the mean peak PRA was 16%, and the mean body mass index was 24.

[5] Modeling the continuous covariates with a linear and a quadratic term (the square of the linear term) is necessary due to the relationship between the covariate and the odds graft failure or patient death.

[6] Glomerular Diseases (GM), Tubulointerstitial Diseases (TI), Cystic, Congenital Diseases (CC), Systemic Diseases (SD), Other Disease Diagnosis.

**Table III-14. Expected U.S. 1 Year Graft Survival Rates -- Kidney and Kidney-Pancreas Transplants Stratified by Recipient Age, Disease Diagnosis, Type of Donor, and Primary or Repeat Transplant**

| Age | Diagnosis | Kidney Alone | | | | Kidney-Pancreas | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Cadaveric | | Living | | Cadaveric | | Living | |
| | | Primary | Repeat | Primary | Repeat | Primary | Repeat | Primary | Repeat |
| 5 | Glomerular | 80.3 | 75.3 | 89.5 | 86.5 | 80.4 | 75.5 | 89.6 | 86.6 |
| | Diabetic | 76.8 | 71.3 | 87.4 | 83.9 | 77.0 | 71.5 | 87.5 | 84.0 |
| | Systemic | 79.2 | 74.1 | 88.9 | 85.7 | 79.4 | 74.3 | 89.0 | 85.9 |
| | Tubulointerstitial | 82.0 | 77.4 | 90.6 | 87.8 | 82.2 | 77.6 | 90.7 | 87.9 |
| | Cystic/Congenital | 80.3 | 75.3 | 89.5 | 86.5 | 80.4 | 75.5 | 89.6 | 86.6 |
| | Other | 80.3 | 75.3 | 89.5 | 86.5 | 80.4 | 75.5 | 89.6 | 86.6 |
| 25 | Glomerular | 86.9 | 83.3 | 93.3 | 91.3 | 87.0 | 83.4 | 93.4 | 91.4 |
| | Diabetic | 84.3 | 80.2 | 91.9 | 89.5 | 84.5 | 80.3 | 92.0 | 89.6 |
| | Systemic | 86.2 | 82.4 | 92.9 | 90.7 | 86.3 | 82.5 | 93.0 | 90.8 |
| | Tubulointerstitial | 88.2 | 84.8 | 94.0 | 92.1 | 88.3 | 85.0 | 94.1 | 92.2 |
| | Cystic/Congenital | 86.9 | 83.3 | 93.3 | 91.3 | 87.0 | 83.4 | 93.4 | 91.4 |
| | Other | 86.9 | 83.3 | 93.3 | 91.3 | 87.0 | 83.4 | 93.4 | 91.4 |
| 40 | Glomerular | 88.0 | 84.7 | 93.9 | 92.1 | 88.2 | 84.8 | 94.0 | 92.1 |
| | Diabetic | 85.7 | 81.8 | 92.6 | 90.4 | 85.8 | 81.9 | 92.7 | 90.5 |
| | Systemic | 87.3 | 83.8 | 93.5 | 91.6 | 87.5 | 84.0 | 93.6 | 91.7 |
| | Tubulointerstitial | 89.2 | 86.1 | 94.6 | 92.9 | 89.3 | 86.2 | 94.6 | 92.9 |
| | Cystic/Congenital | 88.0 | 84.7 | 93.9 | 92.1 | 88.2 | 84.8 | 94.0 | 92.1 |
| | Other | 88.0 | 84.7 | 93.9 | 92.1 | 88.2 | 84.8 | 94.0 | 92.1 |
| 50 | Glomerular | 87.4 | 83.9 | 93.6 | 91.6 | 87.6 | 84.1 | 93.7 | 91.7 |
| | Diabetic | 85.0 | 80.9 | 92.2 | 89.9 | 85.1 | 81.1 | 92.3 | 90.0 |
| | Systemic | 86.7 | 83.0 | 93.2 | 91.1 | 86.8 | 83.2 | 93.3 | 91.2 |
| | Tubulointerstitial | 88.6 | 85.4 | 94.3 | 92.5 | 88.8 | 85.6 | 94.3 | 92.6 |
| | Cystic/Congenital | 87.4 | 83.9 | 93.6 | 91.6 | 87.6 | 84.1 | 93.7 | 91.7 |
| | Other | 87.4 | 83.9 | 93.6 | 91.6 | 87.6 | 84.1 | 93.7 | 91.7 |
| 65 | Glomerular | 84.1 | 79.9 | 91.7 | 89.3 | 84.3 | 80.1 | 91.8 | 89.4 |
| | Diabetic | 81.1 | 76.3 | 90.0 | 87.1 | 81.3 | 76.5 | 90.1 | 87.3 |
| | Systemic | 83.2 | 78.8 | 91.3 | 88.7 | 83.4 | 79.0 | 91.3 | 88.8 |
| | Tubulointerstitial | 85.6 | 81.7 | 92.6 | 90.4 | 85.7 | 81.8 | 92.7 | 90.4 |
| | Cystic/Congenital | 84.1 | 79.9 | 91.7 | 89.3 | 84.3 | 80.1 | 91.8 | 89.4 |
| | Other | 84.1 | 79.9 | 91.7 | 89.3 | 84.3 | 80.1 | 91.8 | 89.4 |

**Table III-15. Expected U.S. 1 Year Patient Survival Rates -- Kidney and Kidney-Pancreas Transplants Stratified by Recipient Age, Disease Diagnosis, Type of Donor, and Primary or Repeat Transplant**

| Age | Diagnosis | Kidney Alone | | | | Kidney-Pancreas | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Cadaveric | | Living | | Cadaveric | | Living | |
| | | Primary | Repeat | Primary | Repeat | Primary | Repeat | Primary | Repeat |
| 5 | Glomerular | 98.1 | 97.7 | 98.9 | 98.7 | 97.2 | 96.6 | 98.4 | 98.1 |
| | Diabetic | 96.5 | 95.7 | 98.0 | 97.5 | 95.0 | 93.9 | 97.1 | 96.4 |
| | Systemic | 97.8 | 97.3 | 98.7 | 98.4 | 96.8 | 96.1 | 98.1 | 97.7 |
| | Tubulointerstitial | 98.1 | 97.7 | 98.9 | 98.7 | 97.2 | 96.6 | 98.4 | 98.1 |
| | Cystic/Congenital | 98.3 | 97.9 | 99.0 | 98.8 | 97.6 | 97.0 | 98.6 | 98.3 |
| | Other | 97.7 | 97.2 | 98.7 | 98.4 | 96.7 | 96.0 | 98.1 | 97.7 |
| 25 | Glomerular | 98.0 | 97.5 | 98.8 | 98.6 | 97.0 | 96.4 | 98.3 | 97.9 |
| | Diabetic | 96.3 | 95.5 | 97.8 | 97.4 | 94.6 | 93.5 | 96.9 | 96.2 |
| | Systemic | 97.6 | 97.1 | 98.6 | 98.3 | 96.6 | 95.8 | 98.0 | 97.6 |
| | Tubulointerstitial | 98.0 | 97.5 | 98.8 | 98.6 | 97.0 | 96.4 | 98.3 | 97.9 |
| | Cystic/Congenital | 98.2 | 97.8 | 99.0 | 98.7 | 97.4 | 96.8 | 98.3 | 98.2 |
| | Other | 97.6 | 97.0 | 98.6 | 98.3 | 96.5 | 95.7 | 98.5 | 97.5 |
| 40 | Glomerular | 97.1 | 96.5 | 98.4 | 98.0 | 95.9 | 95.0 | 97.6 | 97.1 |
| | Diabetic | 94.8 | 93.7 | 97.0 | 96.3 | 92.5 | 91.0 | 95.6 | 94.7 |
| | Systemic | 96.7 | 95.9 | 98.1 | 97.6 | 95.2 | 94.1 | 97.2 | 96.6 |
| | Tubulointerstitial | 97.1 | 96.5 | 98.4 | 98.0 | 95.9 | 95.0 | 97.6 | 97.1 |
| | Cystic/Congenital | 97.5 | 96.9 | 98.5 | 98.2 | 96.3 | 95.5 | 97.9 | 97.4 |
| | Other | 96.6 | 95.8 | 98.0 | 97.6 | 95.1 | 94.0 | 97.1 | 96.5 |
| 50 | Glomerular | 95.9 | 95.0 | 97.6 | 97.1 | 94.1 | 92.8 | 96.6 | 95.8 |
| | Diabetic | 92.6 | 91.1 | 95.7 | 94.7 | 89.5 | 87.4 | 93.8 | 92.4 |
| | Systemic | 95.2 | 94.2 | 97.2 | 96.6 | 93.2 | 91.7 | 96.0 | 95.1 |
| | Tubulointerstitial | 95.9 | 95.0 | 97.6 | 97.1 | 94.1 | 92.8 | 96.6 | 95.8 |
| | Cystic/Congenital | 96.4 | 95.6 | 97.9 | 97.4 | 94.7 | 93.6 | 96.9 | 96.3 |
| | Other | 95.1 | 94.0 | 97.2 | 96.5 | 93.0 | 91.5 | 95.9 | 95.0 |
| 65 | Glomerular | 91.5 | 89.8 | 95.0 | 93.9 | 88.0 | 85.7 | 92.8 | 91.3 |
| | Diabetic | 85.3 | 82.4 | 91.1 | 89.2 | 79.8 | 76.2 | 87.4 | 84.9 |
| | Systemic | 90.2 | 88.2 | 94.2 | 92.9 | 86.3 | 83.6 | 91.7 | 90.0 |
| | Tubulointerstitial | 91.5 | 89.8 | 95.0 | 93.9 | 88.0 | 85.7 | 92.8 | 91.3 |
| | Cystic/Congenital | 92.4 | 90.8 | 95.6 | 94.6 | 89.3 | 87.1 | 93.6 | 92.2 |
| | Other | 90.0 | 87.9 | 94.0 | 92.8 | 85.9 | 83.2 | 91.5 | 89.7 |

## J. SUMMARY

### Study Period

The 1997 Report was based on 62,572 kidney transplants performed in 60,340 patients between January 1, 1988, and April 30, 1994, from 249 transplant programs in the United States. In order to assess changes within transplant programs over time, the data were divided into 2 eras. The first era included transplants performed from January 1, 1988, through April 30, 1992; the second era covered the two year time period from May 1, 1992, through April 30, 1994.

### Survival Rates

Survival rates were computed at 3 months, 1 year, and 3 years, both nationally and for each transplant program. Three year survival was determined in two ways: (1) conditional 3 year survival (i.e., survival at 3 years for those who survived at least 1 year post-transplant), and (2) unconditional 3 year survival. The emphasis on long term survival in this chapter is on the conditional 3-year survival rates because the conditional 3-year analysis provides an assessment of characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

The national graft and patient survival rates and completeness of follow-up at 3 months, 1 year, and conditional 3 years are shown in Tables III-1 and III-2. The percent of programs with graft and patient follow-up data at 1 year was more than 96%; at conditional 3 years the percent of programs with follow-up data was 92%.

There was a marked increase in both the number of kidney transplants and in the actual graft and patient survival rates from Era 1 to Era 2. As demonstrated in Table III-16, graft survival rates increased 2.7% at 3 months and 3.3% at 1 year in Era 2 from Era 1. Patient survival rates increased 0.7% at 3 months and 0.9% at 1 year during the study period.

For the majority of transplant programs, the difference between actual and expected survival rates was not statistically significant (See Figures III-1 and III-3). In general, large differences (either higher or lower) were nearly always found among programs that reported relatively few transplants (see Figure III-2). Therefore, when evaluating survival rates for a program, it is also important to consider the number of transplants performed there.

**Table III-16. Comparison of 3 Month and 1 Year Actual Survival Rates Between Eras**

| | 3 Months | | 1 Year | |
|---|---|---|---|---|
| | Era 1 | Era 2 | Era 1 | Era 2 |
| Graft Survival (%) | 87.9% | 90.6% | 82.3% | 85.6% |
| Average No. of Transplants/Month | 791 | 894 | 791 | 894 |
| Patient Survival (%) | 96.9% | 97.6% | 94.0% | 94.9% |
| Average No. of Patients/Month | 769 | 887 | 769 | 887 |

### Differences Between Short Term and Long Term Characteristics

The 1997 Report includes an extensive list of characteristics that have a significant impact on both short and long term graft and patient survival.

Characteristics with the strongest *positive* impact on *short term survival* were:

- Recipient received a living donor transplant
- Recipient was Asian or Hispanic
- Recipient was female

- Year of transplant was 1993 or 1994

Characteristics with the strongest *negative* impact on *short term survival* were:

- Recipient received one or more previous transplants
- Recipient's HLA was poorly matched with donor
- Recipient was in ICU or hospitalized at time of transplant
- Recipient was less than 2 years old
- Recipient had diabetes
- Donor was Black or Hispanic

Characteristics with the strongest *positive* impact on *long term survival* were:

- Recipient received a living donor transplant
- Recipient was female
- Year of Transplant was 1992

Characteristics with the strongest *negative* impact on *long term survival* were:

- Recipient received one or more previous transplants
- Recipient HLA was poorly matched with donor
- Recipient was Black
- Recipient had diabetes or a systemic disease
- Recipient needed dialysis within the first week post-transplant
- Recipient had rejection episodes within the first six months after transplant
- Donor was Black

## K. FINAL WORDS

The purpose of this report is to provide updated information on survival outcomes both nationally and at specific transplant programs, and to enhance the awareness of program performance in the U.S. However, the assessment of a transplant program should not be based solely on the survival rates provided in this report. Some of the other important factors to consider are the experience of the transplant team, support personnel, the cost of the procedure, and the quality and location of post-transplant services.

# IV. LIVER CHAPTER

Introduction
Completeness of Follow-Up Data and Survival Rates
Percentages of Actual and Expected Graft Survival Rates
Percentages of Actual and Expected Patient Survival Rates
Donor and Recipient Characteristics
Impact of Characteristics on Short Term Survival
Impact of Characteristics on Long Term Survival
Comparison Between Short and Long Term Characteristics
Statistical Methods and Models
Summary
Final Words

# IV. LIVER TRANSPLANT SURVIVAL RATES

*For the Summary of this chapter, see page 66. For definitions of any terms used here, please refer to the User's Guide in the Liver volume.*

## A. INTRODUCTION

This report of liver transplant survival rates is based upon verified Scientific Registry data for 16,658 transplants involving 14,607 patients from 103 liver transplant programs in the United States. Each program reporting at least one liver transplant between January 1, 1988, and April 30, 1994, was included. Multi-organ and living donor transplants were excluded.

Short term survival is defined as survival at 3 months and 1 year post-transplant. Short term survival rates are based on all transplants in the study for which there are follow-up data.

Long term survival is defined in two ways:

- unconditional survival at 3 years post-transplant, and
- survival at 3 years post-transplant for those who survived at least 1 year, referred to as **conditional 3 year survival**.

The long term survival rates are based on all transplants between January 1, 1988, and April 30, 1992, for which there are follow-up data. This cohort was chosen to ensure that the maximum number of transplants with follow-up data was used to determine long term survival rates. Please note that the emphasis on long term survival in this report is on the *conditional* 3-year survival rates. This is because the conditional 3-year analysis provides an assessment of characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

## B. COMPLETENESS OF FOLLOW-UP DATA AND OVERALL GRAFT AND PATIENT SURVIVAL RATES

For graft survival, completeness of follow-up data and overall actual survival rates at each time point are shown in Table IV-1; patient survival data are shown in Table IV-2.

Patient (graft) follow-up data were considered complete when:

- the patient was alive (liver was functioning) and the duration of survival (function) was equal to or exceeded the specified time after transplant (i.e., 3 months, 1 or 3 years), or

- the patient died (liver failed) and a valid date of death (failure) was reported.

The percentages of complete follow-up data ranged from a low of 96.5% for the conditional 3 year time point to a high of 99.9% for the 3 month time point.

Overall survival rates also are presented in the tables. Patient survival rates are better than graft survival rates at all time points because patients may be retransplanted and remain alive following graft failure. If a graft had incomplete follow-up data, the observation was weighted to account for the time during which the graft was known to be functioning. Therefore, the actual graft survival rate reflects the weighted proportion of grafts functioning at the specified time interval. Patient survival rates were computed in a similar way (see the *Technical Methods* chapter of the *Executive Summary*).

In the cohort of transplants (1/1/88 - 4/30/92) used to compute conditional 3 year survival rates, patients (grafts) who did not survive to 1 year after transplant were excluded from the analyses. Therefore, the total number of patients (grafts) for the conditional 3 year analysis was less than that for the 3 month and 1 year analyses. Further, the number of patients is greater than the number of grafts because more grafts failed than patients died within the first year post-transplant.

Please note that the conditional 3 year graft and patient survival rates in Tables IV-1 and IV-2 may be higher than the 1 year graft survival rates. This is possible because the conditional 3 year survival rates should be interpreted as the 3 year survival rate for patients (grafts) who (which) survived at least 1 year post-transplant.

For example: Program A performed a total of five transplants between 1/1/88 and 4/30/92. Two of the livers failed prior to 1 year post-transplant and the remaining three livers survived to 3 years after transplant. In this example, Program A has a 1 year graft survival rate of 60% (3 out of 5 livers were functioning at 1 year post-transplant). However, the conditional 3 year survival rate for Program A is 100% because all three livers that were functioning at 1 year after transplant also were functioning at 3 years post-transplant. The same calculations are used for patient survival. See the *Technical Methods* chapter of the *Executive Summary* for more specific definitions of follow-up data and the calculations for actual graft and patient survival.

## Overall Graft and Patient Survival Rates by Era

In this report, short term survival also is reported by era. Separate eras were used to determine whether there were any improvements over time in the short term survival rates. Era 1 is defined as all transplants occurring between January 1, 1988, and April 30, 1992; Era 2 includes all transplants occurring between May 1, 1992, and April 30, 1994. The overall graft and patient survival rates by era are presented in the last two columns of Table IV-1 and Table IV-2, respectively. The results demonstrate a substantial improvement in both graft and patient survival rates over time.

**Table IV-1. Completeness of Graft Follow-Up Data and Actual Survival Rates for Liver Transplants**

| Time | Cohort | Number of Transplants | Percent with Follow-Up Data | Graft Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 3 Months | 1/1/88 - 4/30/94 | 16,658 | 99.9 | 77.7 | 75.5 | 81.1 |
| 1 Year | 1/1/88 - 4/30/94 | 16,658 | 99.1 | 69.9 | 67.3 | 74.1 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 6,859 | 96.8 | 89.0 | 89.0 | N/A* |

**Table IV-2. Completeness of Patient Follow-Up Data and Actual Survival Rates for Liver Transplants**

| Time | Cohort | Number of Patients | Percent with Follow-Up Data | Patient Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 3 Months | 1/1/88 - 4/30/94 | 14,607 | 99.7 | 85.3 | 83.7 | 87.8 |
| 1 Year | 1/1/88 - 4/30/94 | 14,607 | 98.5 | 98.5 | 76.9 | 82.2 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 6,861 | 96.5 | 90.4 | 90.4 | N/A* |

* The cohort used to determine the overall conditional 3 year survival rate is the same as the Era 1 cohort. Therefore, the overall conditional 3 year survival rates are identical to the conditional 3 year survival rates for Era 1. There is no conditional 3 year survival rate calculated for Era 2 due to insufficient follow-up data on patients who received transplants in Era 2.

## C. GRAFT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

For each transplant program, actual and expected survival rates were calculated at 3 months, 1 year, and 3 years conditional on survival at 1 year. Survival rates at each time point were determined using a specific cohort of transplants (shown in Tables IV-1 and IV-2 on the previous page). Expected survival rates were determined for each transplant program based on its specific patient and donor characteristics. These expected outcomes were statistically adjusted for many important prognostic variables, or covariates, that were used in the survival analysis. In other words, they take into account the many different characteristics that affect survival. *For example: if Program A transplanted many more "high risk" recipients than Program B, then Program A would have a lower expected survival rate than Program B.*

If a program's *actual* survival rate was *greater* than its expected survival rate, this means that the program's actual results were higher than the national results for transplants *with the same donor and recipient characteristics*. If a program's *actual* survival rate was *less than* its expected survival rate, this means that the program's actual results were lower than the national results for transplants *with the same donor and recipient characteristics. The difference between the actual and expected rate may have occurred by chance and, therefore, may not be statistically significant.* Furthermore, even a statistically significant difference, one that most likely did not occur by chance, may not be clinically significant (i.e., medically important). A formal description of the methods used to determine actual and expected survival rates appears in the *Technical Methods* chapter of the *Executive Summary*.

Table IV-3 shows the percentages of liver transplant programs by graft survival rates, both for actual and expected survival. The majority of the transplant programs had actual survival rates greater than 60% at all time points. At 3 months, 39% of programs had actual survival rates greater than 80%. At 1 year, this fell to 16%. However, the percentage increased to 89% for the conditional 3 year survival rates. The distribution of the expected survival rates shows a similar trend. The results indicate that there are more programs with high survival rates (>80%) at the conditional 3 year time point than there are at the 3 month and 1 year time point. *This is because the most critical period of time for graft survival is the first year post-transplant.* Those who survive the first year are very likely to survive 3 years post-transplant.

The percentages of programs by short term graft survival rates and eras, both for actual and expected survival, are summarized in Table IV-4. The results demonstrate a substantial improvement in graft survival over time because a greater percentage of programs had actual survival rates higher than 80% in Era 2. Expected survival rates in Era 2 also were higher than in Era 1.

**Table IV-3. Percentages of Liver Transplant Programs by Graft Survival Rates**

| Graft Survival Rates (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 3 Months (n= 103) | 1 Year (n=103) | Cond. 3 Yrs (n=85) | 3 Months (n=103) | 1 Year (n=103) | Cond. 3 Yrs (n=85) |
| 0-40 | 4.9 | 8.7 | 1.2 | 0.0 | 0.0 | 0.0 |
| >40-60 | 7.8 | 20.4 | 0.0 | 0.0 | 0.0 | 1.2 |
| >60-80 | 48.5 | 55.3 | 9.4 | 49.5 | 96.1 | 1.2 |
| >80-90 | 30.1 | 12.6 | 37.6 | 50.5 | 3.9 | 60.0 |
| >90-100 | 8.7 | 3.0 | 51.8 | 0.0 | 0.0 | 37.6 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Table IV-4. Percentages of Liver Transplant Programs by Graft Survival Rates and Era**

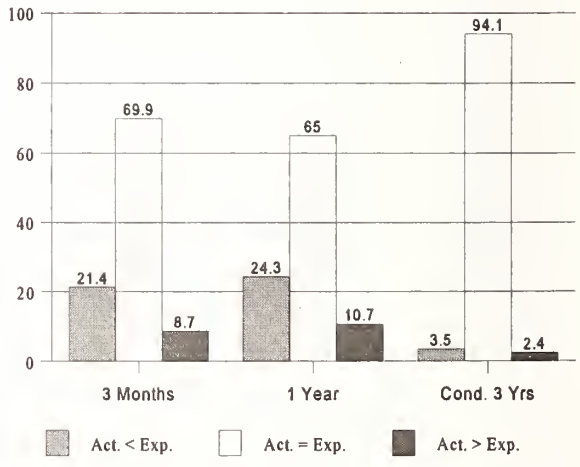
| Graft Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Era 1 (n=90) | Era 2 (n=99) | Era 1 (n=90) | Era 2 (n=99) | Era 1 (n=90) | Era 2 (n=99) | Era 1 (n=90) | Era 2 (n=99) |
| 0-40 | 4.4 | 6.0 | 6.7 | 12.1 | 0.0 | 0.0 | 0.0 | 0.0 |
| >40-60 | 15.6 | 9.1 | 22.2 | 8.1 | 0.0 | 0.0 | 1.1 | 0.0 |
| >60-80 | 52.2 | 29.3 | 62.2 | 47.5 | 71.1 | 31.3 | 95.6 | 87.9 |
| >80-90 | 22.2 | 37.4 | 5.6 | 26.3 | 28.9 | 68.7 | 3.3 | 12.1 |
| >90-100 | 5.6 | 18.2 | 3.3 | 6.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Differences in Actual and Expected Survival Rates**

For most programs, the difference between the actual survival rate and the expected survival rate was not statistically significant. Figure IV-1 shows the percentages of programs whose actual graft survival rates were either above, equal to, or below expected graft survival rates at three time points. Programs with actual survival rates that were not significantly different from expected rates are shown in the actual survival equals expected survival group. Actual survival rates shown in the figure to be either greater than or less than expected survival rates were statistically significant. Overall, there were more programs that fell significantly below expected results than above expected results. However, for the majority of the transplant programs, the difference in actual and expected graft survival was not statistically significant. This was especially true at the conditional 3 year time point where less than 6% of programs were either significantly greater than or significantly less than expected.

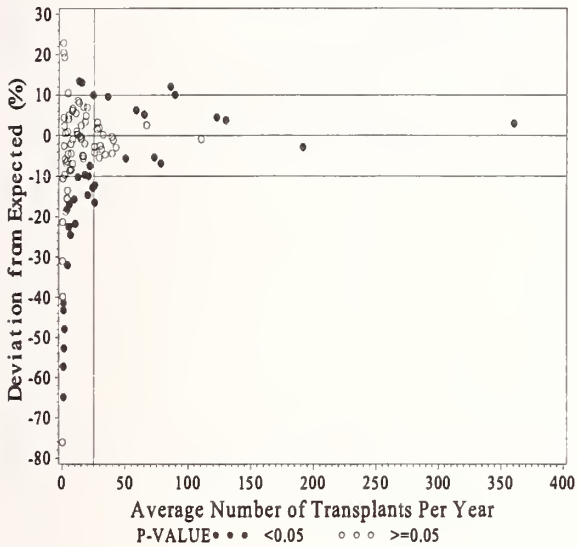
At all time points, the larger differences in actual and expected rates were nearly always seen in programs that reported relatively few transplants during the period. This occurs because programs that do not perform many transplants tend to have highly variable outcomes. To illustrate this, Figure IV-2 shows a scatter plot of the average number of transplants per year (transplant volume) versus the difference in 1 year actual and expected graft survival. Nearly all differences greater than 10% (either positive or negative) are found among transplant programs performing fewer than 25 liver transplants per year. Please note that actual survival rates which differ from expected survival rates are not always statistically significant and even statistically significant differences may not be clinically significant.

**Figure IV-1. Percentages of Liver Transplant Programs with Actual Graft Survival Rates Above, Below, or Equal to Expected Survival Rates. ***




*Actual survival rates above or below expected survival rates are statistically significant.

**Figure IV-2. Liver Transplant Volume vs Difference in Actual and Expected 1 Year Graft Survival**




## D. PATIENT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

The percentages of programs by patient survival rates for both actual and expected survival are shown in Table IV-5; the percentages of programs by survival rates and eras are shown in Table IV-6. Note that both actual and expected patient survival rates were higher at each time point than were actual and expected graft survival rates. As with graft survival, the outcomes in Era 2 were better than in Era 1.

**Table IV-5. Percentages of Liver Transplant Programs by Patient Survival Rates**

| Patient Survival Rates (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 3 Months (n= 103) | 1 Year (n=103) | Cond. 3 Yrs (n=85) | 3 Months (n=103) | 1 Year (n=103) | Cond. 3 Yrs (n=85) |
| 0-40 | 1.9 | 5.8 | 0.0 | 0.0 | 0.0 | 0.0 |
| >40-60 | 6.8 | 8.7 | 0.0 | 0.0 | 0.0 | 1.2 |
| >60-80 | 22.3 | 47.6 | 4.7 | 1.9 | 27.2 | 0.0 |
| >80-90 | 49.6 | 30.1 | 29.4 | 87.4 | 72.8 | 23.5 |
| >90-100 | 19.4 | 7.8 | 65.9 | 10.7 | 0.0 | 75.3 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

Table IV-6. Percentages of Liver Transplant Programs by Patient Survival Rates and Era

| Patient Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Era 1 (n=90) | Era 2 (n=99) | Era 1 (n=90) | Era 2 (n=99) | Era 1 (n=90) | Era 2 (n=99) | Era 1 (n=90) | Era 2 (n=99) |
| 0-40 | 3.3 | 4.0 | 6.7 | 5.1 | 0.0 | 0.0 | 0.0 | 0.0 |
| >40-60 | 11.1 | 7.1 | 12.2 | 8.1 | 0.0 | 0.0 | 0.0 | 0.0 |
| >60-80 | 31.1 | 9.1 | 48.9 | 30.3 | 7.7 | 0.0 | 53.3 | 18.2 |
| >80-90 | 35.6 | 43.4 | 25.5 | 39.3 | 85.6 | 72.7 | 45.6 | 81.8 |
| >90-100 | 18.9 | 36.4 | 6.7 | 17.2 | 6.7 | 27.3 | 1.1 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Differences in Actual and Expected Survival Rates**

The percentage of programs with actual patient survival rates significantly above their expected rates was greater at 3 months and 1 year than at conditional 3 years (see Figure IV-3). Overall, there were more programs that fell significantly below expected results than above expected results. However, for the majority of transplant programs, the difference in actual and expected patient survival was not statistically significant. This was especially true at the conditional 3 year time point where less than 5% of programs were either significantly greater than or significantly less than expected.

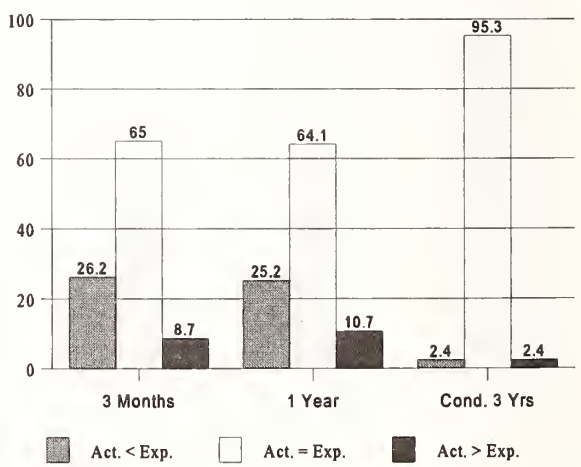
## E. NATIONAL DISTRIBUTION OF DONOR AND RECIPIENT CHARACTERISTICS

The national distribution of donor and recipient characteristics for liver transplants, presented in percentages, is shown in Table IV-7. Each of these donor and recipient characteristics was included in the analyses for graft or patient survival, and used to determine an expected survival rate for each transplant.

The majority of livers transplanted were recovered from white male donors between the ages of 18 and 44 and the most frequent causes of death were due to cerebrovascular accidents (CVAs) and head trauma. Nearly 47% of liver donors had cold ischemic times of 10 hours or less.

The majority of liver recipients were white males between the ages of 45 and 64. Nearly 51% of recipients were not hospitalized prior to transplant and 87% of the recipients received an ABO identical transplant; in other words, both the donor and recipient had the same blood type. Of the 16,658 transplants, 13% were repeat liver transplants.

**Figure IV-3. Percentages of Liver Transplant Programs with Actual Patient Survival Rates Above, Below, or Equal to Expected Survival Rates. ***




*Actual survival rates above or below expected survival rates are statistically significant.

Table IV-7. National Donor and Recipient Characteristics in Liver Transplants: Percentages by Era and Overall

| Characteristics by Category | | ERA 1 1/88-4/92 N=10,241 | ERA 2 5/92-4/94 N=6,417 | OVERALL 1/88-4/94 N=16,658 |
|---|---|---|---|---|
| Donor Age | < 1 | 3.6 | 1.7 | 2.9 |
| | 1-5 | 7.1 | 4.6 | 6.1 |
| | 6-17 | 20.5 | 19.8 | 20.2 |
| | 18-44 | 54.2 | 49.5 | 52.4 |
| | 45-64 | 13.8 | 21.1 | 16.6 |
| | 65+ | 0.5 | 3.2 | 1.5 |
| | Not Reported | 0.3 | 0.2 | 0.2 |
| Donor Race | White | 81.9 | 77.4 | 80.2 |
| | Black | 9.5 | 11.7 | 10.4 |
| | Hispanic | 6.6 | 8.4 | 7.3 |
| | Asian | 0.9 | 1.4 | 1.1 |
| | Other | 0.7 | 0.8 | 0.7 |
| | Not Reported | 0.4 | 0.3 | 0.4 |
| Donor Gender | Female | 35.9 | 36.9 | 36.3 |
| | Male | 64.0 | 63.1 | 63.7 |
| | Not Reported | 0.1 | 0.0 | 0.1 |
| Cold Ischemic Time (Hours) | 0-5 | 11.1 | 9.1 | 10.3 |
| | 6-10 | 34.4 | 40.0 | 36.6 |
| | 11-15 | 31.6 | 32.5 | 31.9 |
| | 16-20 | 11.5 | 7.5 | 10.0 |
| | 21 + | 5.0 | 3.7 | 4.5 |
| | Not Reported | 6.4 | 7.1 | 6.7 |
| Donor Cause of Death | CVA | 28.5 | 34.1 | 30.7 |
| | Head Trauma | 32.8 | 15.9 | 26.3 |
| | Other | 38.8 | 49.9 | 43.1 |

| | | ERA 1 | ERA 2 | OVERALL |
|---|---|---|---|---|
| **Blood Group Compatibility** | Identical | 85.7 | 89.0 | 87.0 |
| | Compatible | 10.4 | 8.6 | 9.7 |
| | Incompatible | 3.4 | 2.2 | 3.0 |
| | Unknown | 0.4 | 0.2 | 0.3 |
| **Recipient Age** | < 1 | 5.1 | 3.3 | 4.4 |
| | 1-5 | 7.6 | 5.8 | 6.9 |
| | 6-17 | 6.3 | 5.2 | 5.9 |
| | 18-44 | 34.5 | 30.9 | 33.1 |
| | 45-64 | 43.1 | 49.5 | 45.5 |
| | 65+ | 3.4 | 5.3 | 4.2 |
| **Recipient Race** | White | 78.2 | 76.3 | 77.5 |
| | Black | 8.2 | 7.7 | 8.0 |
| | Hispanic | 7.7 | 9.7 | 8.4 |
| | Asian | 2.8 | 3.1 | 2.9 |
| | Other | 3.1 | 3.2 | 3.1 |
| | Not Reported | 0.1 | 0.0 | 0.1 |
| **Recipient Gender** | Female | 46.6 | 44.5 | 45.8 |
| | Male | 53.4 | 55.5 | 54.2 |
| **Procedure Type** | Whole Liver | 98.1 | 98.1 | 98.1 |
| | Reduced/Split Liver | 1.9 | 1.9 | 1.9 |
| **Previous Liver Tx** | No | 85.8 | 88.4 | 86.8 |
| | Yes | 14.2 | 11.6 | 13.2 |
| **Liver Disease** | Acute Hepatic Necrosis | 7.7 | 6.7 | 7.4 |
| | Cholestatic/Biliary Cirrhosis | 18.5 | 17.2 | 18.0 |
| | Cirrhosis | 49.2 | 57.2 | 52.3 |
| | Malignant Neoplasms | 4.9 | 3.5 | 4.4 |
| | Metabolic Disease | 5.5 | 4.7 | 5.2 |
| | Miscellaneous Disease | 14.2 | 10.5 | 12.7 |
| | Not Reported | 0.0 | 0.2 | 0.1 |

| | | ERA 1 | ERA 2 | OVERALL |
|---|---|---|---|---|
| **Recipient Description at Transplant** | Intensive Care | 31.0 | 22.4 | 27.7 |
| | Hospitalized | 22.2 | 19.8 | 21.3 |
| | Not Hospitalized | 46.8 | 57.4 | 50.9 |
| | Not Reported | 0.0 | 0.3 | 0.2 |
| **Recipient on Life Support** | No | 79.6 | 85.2 | 81.8 |
| | Yes | 20.4 | 14.4 | 18.1 |
| | Not Reported | 0.0 | 0.3 | 0.1 |
| **Serum Creatinine Prior to Transplant** | 0 - 2 | 85.8 | 86.8 | 86.2 |
| | > 2 | 13.1 | 12.7 | 13.0 |
| | Not Reported | 1.0 | 0.5 | 0.8 |
| **Year of Transplant** | 1988 | 16.4 | 0.0 | 10.1 |
| | 1989 | 21.0 | 0.0 | 12.9 |
| | 1990 | 25.5 | 0.0 | 15.7 |
| | 1991 | 28.0 | 0.0 | 17.2 |
| | 1992 | 9.1 | 31.5 | 17.8 |
| | 1993 | 0.0 | 52.0 | 20.0 |
| | 1994 | 0.0 | 16.5 | 6.4 |

## Donor Trends

National donor characteristics changed between Era 1 and Era 2. The percentage of donors age 45 and older increased by 10% between Era 1 and Era 2, from 14% to 24%. The percentage of minority donors also increased, from 18% to 23%. There were fewer donors who died from head trauma and more who died from cerebrovascular accidents (CVAs).

## Recipient Trends

Transplant recipients were older in the second era; those over age 45 comprised 55% of recipients in Era 2 as compared to 47% in Era 1. The percentage of transplants for patients in the miscellaneous liver disease group decreased, while those with cirrhosis increased in Era 2 (see Table IV-8 for a complete list of primary disease diagnoses). More recipients were not hospitalized prior to their transplants in Era 2; the percentage of recipients who were hospitalized decreased by 2% from Era 1 and the percentage of patients in the intensive care unit decreased by 9% from Era 1.

Despite more older donors and older recipients in Era 2, the national survival rates improved from Era 1 to Era 2 (See Tables IV-1 and IV-2).

**Table IV-8. Liver Primary Disease Diagnoses at Time of Transplant**

| | |
|---|---|
| **Cholestatic Liver Disease/Biliary Cirrhosis**<br><br>Cholestatic Liver Disease<br>Primary Biliary Cirrhosis (PBC)<br>Secondary Biliary Cirrhosis (SBC)<br>--Caroli's disease<br>--Choledochal Cyst<br>--Bile Duct Strictures<br>Primary Sclerosing Cholangitis (PSC)<br>--with Crohn's GI tract disease<br>--with Ulcerative Colitis | **Cirrhosis**<br><br>Cirrhosis:<br>--Laennec's<br>--Postnecrotic Cirrhosis (A, B, C, D)<br>--Postnecrotic Cirrhosis (Non A, Non B)<br>--Cryptogenic, Idiopathic, no obvious source<br>--Chronic Active Hepatitis (A, B, C, D)<br>--Chronic Active Hepatitis: etiology unknown<br>--Autoimmune, Lupoid, Banti's<br>--Drug or industrial exposure |
| **Acute Hepatic Necrosis (AHN)**<br><br>Due to a drug, chemicals, toxins<br>Hepatitis (A, B, C, D)<br>Non A, Non B Hepatitis<br>Acute non-hepatic viral infection<br>Unspecified fulminant hepatitis, submassive hepatic necrosis | **Metabolic Disease**<br><br>Alpha-1-antitrypsin deficiency (A-1-A)<br>Wilson's Disease, Other copper metabolism disorder<br>Hemochromatosis, hemosiderosis, other iron storage disease<br>Glycogen Storage Disease Type I, Type II<br>Hyperlipidemia-II, Homozygous Hypercholesterolemia<br>Tyrosinemia<br>Primary Oxalosis/Oxaluria, Hyperoxaluria<br>Other Metabolic Disease |
| **Miscellaneous (Other) Liver Disease**<br><br>Familial Cholestasis: Byler's Disease, Other<br>Neonatal Hepatitis<br>Biliary Atresia<br>--Extrahepatic, Hypoplasia, Alagille's Syndrome<br>Congenital Hepatic Fibrosis<br>Cystic Fibrosis<br>Budd-Chiari Syndrome<br>Benign Tumor: Hepatic Adenoma, Polycystic liver disease, other<br>Total Parenteral Nutrition (TPN)/Hyperalimentation induced liver disease<br>Graft vs Host Disease secondary to non-liver transplant<br>Trauma | **Malignant Neoplasms**<br><br>Primary Liver Malignancy<br>--Hepatoma, hepatocellular carcinoma (HCC)<br>--Fibrolamellar (FL-HC)<br>--Cholangiocarcinoma (CH-CA)<br>--Hepatoblastoma (HBL)<br>--Hemangioendothelioma, Hemangiosarcoma, Angiosarcoma<br>--Klatskin tumor, Leimyosarcoma<br>Bile duct cancer<br>--Cholangioma, Biliary Tract Carcinoma<br>Secondary Hepatic Malignancy<br>--Non-liver Adenocarcinoma, Cystadenocarcinoma, VIPoma, Gastrinoma, Insulinoma, Islet cell tumor, Neuroendocrine tumor |

## F. SHORT TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

To determine the expected survival for each transplant or patient, separate analyses were performed for graft and patient survival at three time points. (The analyses were performed using logistic regression, see the *Technical Methods* chapter in the *Executive Summary.*) The analyses also identified donor and recipient characteristics that had a significant impact on survival outcomes. For each *characteristic* (e.g., race, gender) considered in the analyses, a *reference group* was chosen (e.g., White, male) with which the other groups were compared. As a general rule, the largest group or the mean of

the characteristic (e.g., mean recipient age=40) was used as the reference group.

The following served as the characteristics and reference groups for ***short term graft and patient*** survival:

- Mean Donor Age -- 28 years
- Donor Race -- non-Black, non-Hispanic
- Donor Gender -- male
- Mean Cold Ischemic Time -- 11 hours
- Donor Cause of Death -- not cerebrovascular accident (CVA)
- Blood Type Compatibility -- identical
- Previous Liver Transplant -- no
- Mean Recipient Age -- 40 years
- Recipient Race -- non-Black, non-Asian
- Transplant Procedure Type -- whole liver
- Primary Liver Disease -- recipient had cirrhosis or metabolic disease (see Table IV-8 for a complete list of primary disease diagnoses)
- Medical Status -- not hospitalized prior to transplant
- Life Support Status -- none
- Serum Creatinine prior to transplant -- ≤ 2 mg/dl
- Year of Transplant -- 1988 or 1989

The relative impact of each donor and recipient characteristic on short term graft and patient survival outcomes is listed in Table IV-9. For each characteristic, the ***odds ratio*** is the odds of patient death (graft failure) as compared to the reference group, after adjusting for the effects of all other donor and recipient characteristics. An *odds ratio of less than 1* indicates that the characteristic was associated with a *reduced odds* of patient death or graft failure relative to the reference group. An odds ratio of *greater than 1* indicates that the characteristic was associated with an *increased odds* of patient death or graft failure relative to the reference group. The corresponding p-value measures the significance of the odds ratio. A p-value less than 0.05 indicates statistical significance and means that there is less than a 5% probability that such difference is due to chance alone. The smaller the p-value, the greater the statistical significance and the less likely the difference is due to chance alone.

**Examples**

In Table IV-9, the odds ratio of graft failure within 3 months after a repeat transplant versus a first, or primary, transplant was 1.59. This means that, after adjusting for all of the other donor and recipient characteristics, the odds of graft failure within 3 months was 59% greater for repeat transplants than for primary transplants ((1.59-1)×100%=59%). As another example, the odds ratio of graft failure within 3 months post-transplant for a recipient who was on life support prior to transplant versus a recipient who was not on life support was 1.71. After adjusting for the effects of both donor and recipient characteristics, the odds of graft failure within 3 months for a patient who was on life support prior to transplant was 71% higher ((1.71-1)×100%=71%) than that for a patient who was not on life support prior to transplant.

The estimated odds ratios for continuous variables (i.e., variables with many possible values) such as cold ischemic time and donor and recipient ages are less easily interpreted. For these variables, the estimated odds is determined for every 1 or 10 unit increase or decrease from the mean (reference group) of the variable. For example, in Table IV-9, the estimated odds of 3 month graft failure for 12 hours of cold ischemic time compared to the mean of 11 hours is 1.02. This means that, after adjusting for the effects of all other characteristics, the odds of graft failure was estimated to increase by 2% for the first one hour increase from the mean cold ischemic time.

An increase of 5 hours from the mean (i.e., the cold ischemic time is 11+5=16 hours) would result in an 8% increase in the odds of graft failure. Mathematically, this 8% was calculated as follows:

$$\text{Odds ratio} = \exp^{\left(\frac{5}{1}\times 0.015\right)} = 1.08$$

where 1 represents the unit of increase and 0.015 corresponds to the coefficient of cold ischemic time per one hour difference (see Table IV-12 for coefficients). Therefore, the increase in the odds of graft failure is (1.08-1)×100%=8%. For some variables such as donor and recipient age, it is necessary to add a quadratic term. For more details on calculating odds ratios for continuous variables, refer to the section on *Odds Ratios* in the *Technical Methods* chapter of the *Executive Summary*.

**Table IV-9. Impact of Donor and Recipient Characteristics on Short Term Graft and Patient Survival--Liver Transplants**

| Short Term Characteristics | Graft Survival | | | | Patient Survival | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Odds Ratio | P-value | Odds Ratio | P-value | Odds Ratio | P-value | Odds Ratio | P-value |
| Donor Age 38 vs 28 [1] | 1.106 | <0.001 | 1.131 | <0.001 | 1.060 | 0.006 | 1.081 | 0.012 |
| Donor Black vs White, Asian, Other | 1.507 | <0.001 | 1.609 | <0.001 | 1.373 | <0.001 | 1.405 | <0.001 |
| Donor Hisp vs White, Asian, Other | 1.225 | 0.007 | 1.146 | 0.048 | 1.168 | 0.097 | 1.147 | 0.097 |
| Donor Female vs Male | 1.136 | 0.003 | 1.089 | 0.027 | 1.181 | 0.002 | 1.125 | 0.012 |
| Cold Ischemic Time - 12 vs 11 hours | 1.015 | <0.001 | 1.011 | <0.001 | 1.005 | 0.274 | 1.004 | 0.284 |
| Cause of Death: Cerebrovascular Accident vs Other | 1.223 | <0.001 | 1.135 | 0.007 | 1.108 | 0.111 | 1.049 | 0.400 |
| ABO Compatible vs Identical | 1.246 | <0.001 | 1.210 | 0.001 | 1.267 | 0.002 | 1.271 | <0.001 |
| ABO Incompatible vs Identical | 1.619 | <0.001 | 1.481 | <0.001 | 1.406 | 0.008 | 1.306 | 0.027 |
| Previous Transplant - Yes vs No | 1.586 | <0.001 | 1.647 | <0.001 | 1.955 | <0.001 | 1.983 | <0.001 |
| Recipient Age - 50 vs 40 [1] | 1.104 | <0.001 | 1.112 | <0.001 | 1.207 | <0.001 | 1.234 | 0.001 |
| Recipient Age < 1 vs Age ≥1 | 1.339 | 0.006 | 1.313 | 0.007 | 1.615 | <0.001 | 1.440 | 0.003 |
| Recipient Black vs White, Hisp, Other | 1.157 | 0.038 | 1.172 | 0.015 | 1.349 | <0.001 | 1.349 | <0.001 |
| Recipient Asian vs White, Hisp, Other | 1.023 | 0.843 | 1.539 | <0.001 | 1.147 | 0.313 | 1.767 | <0.001 |
| Reduced or Split Liver vs Whole Tx | 1.429 | 0.008 | 1.569 | <0.001 | 1.274 | 0.168 | 1.487 | 0.012 |
| Acute Hepatic Necrosis vs Cirrhosis, Metabolic Disease | 1.277 | <0.001 | 1.139 | 0.072 | 1.291 | 0.005 | 1.151 | 0.100 |
| Cholestatic Disease/Biliary Cirrhosis vs Cirrhosis, Metabolic Disease | 0.833 | 0.001 | 0.808 | <0.001 | 0.689 | <0.001 | 0.667 | <0.001 |
| Malignant Neoplasms vs Cirrhosis, Metabolic Disease | 1.016 | 0.867 | 1.653 | <0.001 | 1.021 | 0.862 | 1.989 | <0.001 |
| Miscellaneous Disease vs Cirrhosis, Metabolic Disease | 1.293 | 0.002 | 1.152 | 0.066 | 1.278 | 0.020 | 1.120 | 0.235 |
| Hospitalized vs Not Hospitalized | 1.223 | <0.001 | 1.212 | <0.001 | 1.346 | <0.001 | 1.295 | <0.001 |
| ICU vs Not Hospitalized | 1.476 | <0.001 | 1.409 | <0.001 | 1.646 | <0.001 | 1.558 | <0.001 |
| On Life Support vs No Life Support | 1.706 | <0.001 | 1.602 | <0.001 | 1.837 | <0.001 | 1.697 | <0.001 |
| Most Recent Serum Creatinine Prior to Transplant >2 mg/dl | 1.459 | <0.001 | 1.501 | <0.001 | 1.672 | <0.001 | 1.660 | <0.001 |

| Short Term Characteristics | Graft Survival | | | | Patient Survival | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Odds Ratio | P-value | Odds Ratio | P-valuc | Odds Ratio | P-value | Odds Ratio | P-value |
| **Tx Year 1990 vs 1988-89** | 0.844 | 0.006 | 0.822 | <0.001 | 0.789 | 0.003 | 0.815 | 0.003 |
| **Tx Year 1991 vs 1988-89** | 0.778 | <0.001 | 0.762 | <0.001 | 0.836 | 0.019 | 0.827 | 0.005 |
| **Tx Year 1992 vs 1988-89** | 0.683 | <0.001 | 0.664 | <0.001 | 0.698 | <0.001 | 0.707 | <0.001 |
| **Tx Year 1993-94 vs 1988-89** | 0.614 | <0.001 | 0.591 | <0.001 | 0.632 | <0.001 | 0.617 | <0.001 |

Notes:

[1] Odds ratios for donor and recipient age do not have a linear relationship. The odds ratios presented in this table represent 1 (cold ischemic time) or 10 unit (donor and recipient age) increases from the mean of each covariate. The mean donor age was 28. The mean cold ischemic time was 11 hours. The mean recipient age was 40.

## Graft Survival

The donor characteristics with the strongest impact on short term graft survival were donor race, donor cause of death, and blood type compatibility between the donor and the recipient. The odds of 1 year graft failure was 61% higher in transplants from Black donors than those from non-Black and non-Hispanic donors. The odds of 1 year graft failure for ABO incompatible grafts was nearly 50% greater than for ABO identical grafts.

The recipient characteristics that had the strongest impact on short term graft survival were previous transplant, race, procedure type (whole or reduced/split liver), disease diagnosis at transplant, medical condition at transplant, serum creatinine prior to transplant and year of transplant. Repeat transplants had a 59% greater odds of failing within 3 months than did first transplants. Although not statistically significant at 3 months, Asian recipients had an increased odds of graft failure at 1 year of 54% as compared to non-Asian and non-Black recipients. Recipients who were in the ICU prior to transplant had a 41% greater odds of graft failure at 1 year than patients who were not hospitalized prior to transplant. Transplants performed during 1993 and the first four months of 1994 had an almost 40% reduced odds of failure compared to transplants performed in 1988.

## Patient Survival

As seen with graft survival, the donor characteristics with the strongest impact on short term patient survival were donor race and ABO compatibility between the donor and recipient. Donor cause of death did not have a significant effect on short term patient survival in liver recipients ($p > 0.05$). The odds of mortality for recipients of Black donor livers was greater than that for recipients of non-Black and non-Hispanic donor livers. The odds of 1 year mortality for recipients of ABO incompatible livers was 31% greater than for recipients of ABO identical livers. Additionally, recipients of female donor livers had a slightly increased odds of mortality at 3 months and 1 year.

The recipient characteristics with the strongest impact on short term patient survival are similar to those seen with graft survival. Previous transplant, race, disease diagnosis at transplant, medical condition at transplant, and year of transplant were found to influence strongly patient mortality. When compared to those receiving primary transplants, recipients of repeat transplants had an increased odds of mortality of more than 95% at 3 months and 1 year. Although not statistically significant at 3 months, Asian recipients had an increased odds of mortality at 1 year of 77% as compared to non-Asian and non-Black recipients. A similar trend was observed for recipients with a diagnosis of malignant neoplasms; these patients had an increased odds of mortality at 1 year of 99% as compared to recipients

with cirrhosis or metabolic diseases. Recipients of transplants in 1992, 1993, and 1994 had a 29% to 38% reduction in the odds of death at 1 year post-transplant relative to recipients of transplants in 1988. This finding is consistent with the improved liver patient survival rates over time.

## G. LONG TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

In this report, long term survival analyses were developed separately from the short term survival analyses. Because this narrative focuses on conditional 3 year survival (survival at 3 years for grafts or patients surviving at least 1 year post-transplant), only conditional 3 year survival data are presented in this text. Both conditional and unconditional 3 year survival rates are provided in the tables for each transplant program presented in each organ specific volume.

The conditional 3 year survival analyses provide an assessment of the donor and recipient characteristics that are independent of those limited to the first year (e.g., surgical complications).

The impact of each donor and recipient characteristic on graft and patient long term survival is listed in Table IV-10.

**Table IV-10. Impact of Donor and Recipient Characteristics on Long Term Graft and Patient Survival -- Liver Transplants**

| Long Term Characteristics | Graft Survival | | Patient Survival | |
|---|---|---|---|---|
| | Odds Ratio | P-value | Odds Ratio | P-value |
| **Donor Age 38 vs 28** [1] | 1.162 | 0.002 | 1.155 | <0.001 |
| **Donor Female vs Male** | 1.229 | 0.020 | 1.303 | 0.005 |
| **Donor Cause of Death CVA vs Other** | 0.795 | 0.032 | 0.797 | 0.046 |
| **Previous Transplant Yes vs No** | 1.741 | <0.001 | 1.644 | 0.003 |
| **Recipient Age 50 vs 40** [1] | 1.004 | 0.913 | 1.101 | 0.006 |
| **Recipient Age < 1 vs Age ≥1** | 2.047 | 0.003 | 2.507 | <0.001 |
| **Recipient Black vs White, Asian, Hispanic, Other** | 1.647 | <0.001 | 1.643 | 0.002 |
| **Recipient Female vs Male** | 0.806 | 0.011 | 0.781 | 0.006 |
| **Reduced or Split Liver vs Whole Tx** | 2.369 | 0.003 | 3.052 | <0.001 |
| **Acute Hepatic Necrosis vs Cirrhosis** | 0.628 | 0.016 | 0.511 | 0.004 |
| **Cholestatic Disease/Biliary Cirrhosis vs Cirrhosis** | 0.576 | <0.001 | 0.567 | <0.001 |
| **Metabolic Disease vs Cirrhosis** | 0.672 | 0.050 | 0.617 | 0.038 |
| **Malignant Neoplasms vs Cirrhosis** | 5.848 | <0.001 | 6.483 | <0.001 |
| **Miscellaneous Disease vs Cirrhosis** | 0.404 | <0.001 | 0.386 | <0.001 |

Notes:

[1] Odds ratios for donor and recipient age do not have a linear relationship. The odds ratios presented in this table represent 1 (cold ischemic time) or 10 unit (donor and recipient age) increases from the mean of each covariate. The mean donor age was 28. The mean cold ischemic time was 11 hours. The mean recipient age was 40.

The following characteristics and reference groups were used for *long term graft and patient* survival:

- Mean Donor Age -- 28
- Donor Gender -- male
- Donor Cause of Death -- not CVA
- Previous Liver Transplant -- no
- Mean Recipient Age -- 40 years
- Recipient Race -- non-Black
- Recipient Gender -- male
- Transplant Procedure Type -- whole liver
- Primary Liver Disease --recipient had cirrhosis (see Table IV-8 for a complete list of primary disease diagnoses)

Graft Survival

The donor characteristics with the strongest impact on long term graft survival were donor gender and donor cause of death. Based on the conditional 3 year analysis, the odds of graft failure was 20% lower in recipients of livers from donors with cause of death due to CVA than recipients of donors with all other causes of death ((0.8-1) ×100%=-20%); and 23% higher in female donor transplants than in male donor transplants. Donor race and cold ischemic time had no significant effect on long term survival and were not included in the analysis.

The recipient characteristics that had the strongest impact on graft survival were transplant number (primary or repeat), age, race, gender, transplant procedure type (whole or reduced/split liver), and disease diagnosis at transplant. Black recipients had an approximately 65% greater odds of graft failure than did non-Black recipients, while female recipients had a 19% lower odds of graft failure than did male recipients. When compared to the cirrhosis disease group, patients diagnosed with malignant neoplasms had nearly 6 times the odds of graft failure. In contrast, recipients with acute hepatic necrosis, cholestatic disease/biliary cirrhosis, metabolic disease, or miscellaneous diseases had a 33% to 60% lower odds of graft failure when compared to the cirrhosis group.

Patient Survival

As was seen with graft survival, the donor characteristics with the strongest impact on long term patient survival were donor gender and donor cause of death. Based on the conditional 3 year analysis, the odds of mortality was 30% higher in female donor transplants than in male donor transplants; and 20% lower in recipients of livers from donors with cause of death due to CVA than recipients of donors with all other causes of death.

The recipient characteristics that had the strongest impact on long term patient survival were transplant number (primary or repeat) age, race, gender, transplant procedure type (whole vs reduced or split liver), and disease diagnosis at transplant. Recipients under age 1 had a 151% greater odds of graft failure than recipients of all other ages, and Black recipients had an approximately 65% greater odds of mortality than did non-Black recipients. Similar results were also found with respect to recipient diagnosis. When compared to the cirrhosis disease group, patients diagnosed with malignant neoplasms had nearly 6.5 times the odds of mortality. In contrast, recipients with acute hepatic necrosis, cholestatic disease/biliary cirrhosis, metabolic disease, or miscellaneous diseases had significantly lower odds of death when compared to recipients with cirrhosis.

## H. COMPARISON BETWEEN SHORT TERM AND LONG TERM CHARACTERISTICS

Many of the donor and recipient characteristics that had a strong impact on short term graft survival appeared to have a strong impact on long term graft survival as well. Some exceptions were donor race, blood type compatibility between donor and recipient and medical condition prior to transplant. Recipient gender did not have a significant impact on short term patient survival but female recipients had a significantly decreased odds of graft failure and patient mortality in the long term.

For some characteristics, their negative effect on graft and/or patient survival increased over time. For instance, the odds of graft failure at 3 months for recipients with previous transplants was 1.59, then increased to 1.65 at 1 year, and was 1.74 in the conditional 3 years analysis. Similarly, the odds of patient mortality at 3 months for recipients of reduced or split livers compared to recipients of whole livers was 1.27, which increased to 1.49 at 1 year, and 3.05 in the conditional 3 years analysis. In the short term, recipients with a diagnosis of malignant neoplasms showed a moderate increase in

the odds of graft failure compared to patients with cirrhosis or metabolic diseases. In the long term, however, recipients with malignancies had a nearly 484% increased odds of graft failure compared to patients with cirrhosis. Interestingly, while patients with acute hepatic necrosis or miscellaneous diseases had an increased risk of graft failure and patient mortality in the short term, for those grafts (patients) which (who) survived the first year, there was a significantly decreased risk of graft failure and mortality at 3 years.

## I. STATISTICAL METHODS AND MODELS

***This section provides a brief summary of the statistical methods used to determine survival rates for liver transplants, both nationally and at each transplant program. It is <u>not</u> necessary to read this section in order to utilize the rest of the report. For additional statistical details, please see the Technical Methods chapter in the Executive Summary.***

### Model Significance -- $R^2$

The conclusion that there is a "center effect" in liver transplantation often is based on the observation that actual survival rates vary considerably among liver transplant programs. However, in reality, only part of the variability can be attributed to the quality of the program (the so called "center effect"); the rest can be attributed to the differences in donor and recipient characteristics among transplant programs. The degree to which the variability in actual survival rates can be attributed to the specific donor and recipient characteristics in each analysis appears in Table IV-11.

In the table, the values in the column labeled $R^2$ estimate the percentage of variability in the actual survival rates that can be attributed to the covariates in each analysis. *The higher the percentage, the better the analysis explained the individual program outcomes, based on the characteristics examined.* Theoretically, if an analysis contained every covariate that affected survival outcomes, and there were no differences in quality among programs (i.e., no "center effect"), then $R^2$ would equal 100%. In practice, we can never capture every factor that affects outcomes, and it is likely that real differences among programs do exist. This means that any unexplained variation can probably be attributed to a combination of true center effect and covariates not considered in this study. (For details on the $R^2$ calculation, refer to the *Model Significance* section in the *Technical Methods* chapter of the *Executive Summary*.)

The value of $R^2$ estimated from analyses in the 1994 Report was compared to the value of the $R^2$ analyses in the 1997 Report. Note that these analyses are not *directly* comparable since each was used with a different cohort of transplants. Despite the refinements in the 1997 Report, as compared to the 1994 Report, much of the variation in actual survival rates among the 103 transplant programs in the study remains unexplained by the analyses. This suggests that much of the risk involved in liver transplantation is due to characteristics not described in this report.

### Estimated Coefficients and Standard Errors from the Logistic Regression Models

Tables IV-12 and IV-13 list the coefficients and the standard errors of the coefficients at each time point for all of the donor and recipient characteristics used in the logistic regression models. Each coefficient is reported on the logistic scale and represents the $\log_e$ odds of graft failure or the $\log_e$ odds of patient mortality for the corresponding characteristic at the specified time after transplant. The adjusted odds ratio on the probability scale may be obtained by applying the exponential function to the coefficient. For further details, see the *Odds Ratios* section in the *Technical Methods* chapter of the *Executive Summary*.

**Table IV-11. Liver Model $R^2$: Comparison of the 1994 and 1997 Reports**

| Outcome | Time Point | Report Year | Number of Covariates | $R^2$ |
|---|---|---|---|---|
| Graft Model $R^2$ | 3 Months | 1997<br>1994 | 28<br>23 | 34.1<br>40.0 |
| | 1 Year | 1997<br>1994 | 28<br>23 | 38.2<br>34.0 |
| | Cond. 3 Years | 1997<br>1994 | 14<br>N.A.* | 28.3<br>N.A.* |
| Patient Model $R^2$ | 3 Months | 1997<br>1994 | 28<br>23 | 36.2<br>45.0 |
| | 1 Year | 1997<br>1994 | 28<br>23 | 39.9<br>43.0 |
| | Cond. 3 Years | 1997<br>1994 | 14<br>N.A.* | 42.2<br>N.A.* |

* Not applicable, conditional 3 year survival not calculated in the 1994 Report.

**Table IV-12. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Short Term Liver Transplant Survival**

| Short Term Characteristics | Graft Survival | | | | Patient Survival | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| Intercept | -1.859 | 0.059 | -1.329 | 0.053 | -2.439 | 0.075 | -1.920 | 0.065 |
| Donor Age - Linear (per 10 years) [1,2] | 0.083 | 0.019 | 0.101 | 0.018 | 0.044 | 0.024 | 0.066 | 0.022 |
| - Quadratic | 0.018 | 0.007 | 0.015 | 0.007 | 0.014 | 0.009 | 0.013 | 0.008 |
| Donor Black vs White, Asian, Other | 0.410 | 0.061 | 0.476 | 0.057 | 0.317 | 0.078 | 0.340 | 0.069 |
| Donor Hisp vs White, Asian, Other | 0.203 | 0.075 | 0.136 | 0.069 | 0.155 | 0.094 | 0.137 | 0.082 |
| Donor Female vs Male | 0.127 | 0.042 | 0.086 | 0.039 | 0.166 | 0.053 | 0.118 | 0.047 |
| Cold Ischemic Time (per hour) | 0.015 | 0.004 | 0.011 | 0.003 | 0.005 | 0.005 | 0.004 | 0.004 |
| Cause of Death: Cerebrovascular/ Stroke vs Other | 0.201 | 0.051 | 0.127 | 0.047 | 0.103 | 0.064 | 0.048 | 0.057 |
| ABO Compatible vs Identical | 0.220 | 0.062 | 0.190 | 0.058 | 0.237 | 0.077 | 0.239 | 0.070 |
| ABO Incompatible vs Identical | 0.482 | 0.101 | 0.393 | 0.099 | 0.341 | 0.128 | 0.267 | 0.121 |
| Previous Transplant Yes vs No | 0.461 | 0.057 | 0.499 | 0.054 | 0.671 | 0.079 | 0.685 | 0.074 |

| Short Term Characteristics | Graft Survival | | | | Patient Survival | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| **Recipient Age - Linear (per 10 years) [1,2]** | 0.071 | 0.015 | 0.077 | 0.014 | 0.154 | 0.019 | 0.168 | 0.017 |
| **- Quadratic** | 0.028 | 0.007 | 0.030 | 0.006 | 0.035 | 0.009 | 0.042 | 0.008 |
| **Recipient Age < 1 vs Age ≥ 1** | 0.292 | 0.107 | 0.272 | 0.101 | 0.479 | 0.134 | 0.365 | 0.124 |
| **Recipient Black vs White, Hisp, Other** | 0.146 | 0.070 | 0.159 | 0.065 | 0.299 | 0.086 | 0.299 | 0.078 |
| **Recipient Asian vs White, Hisp, Other** | 0.023 | 0.115 | 0.431 | 0.099 | 0.137 | 0.136 | 0.569 | 0.111 |
| **Reduced or Split Liver vs Whole Tx** | 0.357 | 0.135 | 0.451 | 0.129 | 0.242 | 0.175 | 0.397 | 0.158 |
| **Acute Hepatic Necrosis vs Cirrhosis, Metabolic Disease** | 0.244 | 0.076 | 0.130 | 0.073 | 0.255 | 0.092 | 0.141 | 0.086 |
| **Cholestatic Disease/Biliary Cirrhosis vs Cirrhosis, Metabolic Disease** | -0.183 | 0.057 | -0.213 | 0.051 | -0.372 | 0.075 | -0.405 | 0.065 |
| **Malignant Neoplasms vs Cirrhosis, Metabolic Disease** | 0.016 | 0.098 | 0.503 | 0.083 | 0.021 | 0.119 | 0.688 | 0.091 |
| **Miscellaneous Disease vs Cirrhosis, Metabolic Disease** | 0.257 | 0.082 | 0.142 | 0.077 | 0.245 | 0.105 | 0.113 | 0.095 |
| **Hospitalized vs Not Hospitalized** | 0.201 | 0.053 | 0.193 | 0.047 | 0.298 | 0.067 | 0.259 | 0.057 |
| **ICU vs Not Hospitalized** | 0.390 | 0.068 | 0.343 | 0.062 | 0.499 | 0.085 | 0.443 | 0.075 |
| **On Life Support vs No Life Support** | 0.534 | 0.071 | 0.471 | 0.067 | 0.608 | 0.088 | 0.529 | 0.080 |
| **Most Recent Serum Creatinine Prior to Transplant >2 mg/dl** | 0.378 | 0.057 | 0.406 | 0.054 | 0.514 | 0.069 | 0.507 | 0.063 |
| **Tx Year 1990 vs 1988-89** | -0.169 | 0.062 | -0.196 | 0.057 | -0.237 | 0.079 | -0.204 | 0.069 |
| **Tx Year 1991 vs 1988-89** | -0.251 | 0.062 | -0.272 | 0.056 | -0.179 | 0.077 | -0.190 | 0.067 |
| **Tx Year 1992 vs 1988-89** | -0.381 | 0.063 | -0.409 | 0.057 | -0.360 | 0.079 | -0.347 | 0.069 |
| **Tx Year 1993-94 vs 1988-89** | -0.488 | 0.058 | -0.527 | 0.053 | -0.459 | 0.073 | -0.483 | 0.064 |

Notes:

[1] In the analysis, the continuous covariates (donor age, cold ischemic time, recipient age) were centered at their mean. The mean donor age was 28. The mean cold ischemic time was 11 hours. The mean recipient age was 40.

[2] Modeling the continuous covariates with a linear and a quadratic term (the square of the linear term) is necessary due to the relationship between the covariate and the odds of graft failure or patient death.

**Table IV-13. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Long Term Liver Transplant Survival**

| Long Term Characteristics | Graft Survival | | Patient Survival | |
|---|---|---|---|---|
| | Model Coefficient | Standard Error | Model Coefficient | Standard Error |
| **Intercept** | -2.137 | 0.081 | -2.305 | 0.086 |
| **Donor Age -Linear (per 10 years)** [1,2] | 0.110 | 0.038 | 0.100 | 0.041 |
| **-Quadratic** | 0.040 | 0.017 | 0.044 | 0.018 |
| **Donor Female vs Male** | 0.207 | 0.088 | 0.264 | 0.094 |
| **Donor Cause of Death Cerebrovascular/Stroke vs Other** | -0.230 | 0.107 | -0.227 | 0.114 |
| **Previous Transplant - Yes vs No** | 0.554 | 0.117 | 0.497 | 0.165 |
| **Recipient Age (per 10 years)** | 0.004 | 0.032 | 0.096 | 0.035 |
| **Recipient Age < 1 vs Age ≥1** | 0.716 | 0.237 | 0.919 | 0.276 |
| **Recipient Black vs White, Asian, Hispanic, Other** | 0.499 | 0.144 | 0.496 | 0.159 |
| **Recipient Female vs Male** | -0.216 | 0.846 | -0.248 | 0.091 |
| **Reduced or Split Liver vs Whole Tx** | 0.862 | 0.287 | 1.116 | 0.311 |
| **Acute Hepatic Necrosis vs Cirrhosis** | -0.465 | 0.194 | -0.671 | 0.233 |
| **Cholestatic Disease/Biliary Cirrhosis vs Cirrhosis** | -0.553 | 0.121 | -0.567 | 0.128 |
| **Metabolic Disease vs Cirrhosis** | -0.397 | 0.203 | -0.483 | 0.233 |
| **Malignant Neoplasms vs Cirrhosis** | 1.766 | 0.134 | 1.869 | 0.135 |
| **Miscellaneous Disease vs Cirrhosis** | -0.907 | 0.201 | -0.953 | 0.234 |

Notes:

[1] In the analysis, the continuous covariates (donor age, cold ischemic time, recipient age) were centered at their mean. The mean donor age was 28. The mean cold ischemic time was 11 hours. The mean recipient age was 40.

[2] Modeling the continuous covariates with a linear and a quadratic term (the square of the linear term) is necessary due to the relationship between the covariate and the odds of graft failure or patient death.

## Expected Liver Transplant Survival Rates

Table IV-14 shows the 1 year *expected graft* survival rates for liver transplants for a given set of donor and recipient characteristics; Table IV-15 shows the 1 year *expected patient* survival rates. These rates were determined using the following characteristics: recipient age, disease diagnosis, medical status prior to transplant, and transplant number. For these analyses, all other characteristics were set to the values for the reference groups, with the exception of the year of transplant (1993-94). The complete list of reference groups is shown on page 55.

For example, in Table IV-14, the expected 1 year graft survival for a 40 year old primary liver recipient with metabolic disease who was not hospitalized prior to transplant was 87%. In contrast, the expected 1 year graft survival for a primary liver recipient of the same age with metabolic disease who was in the ICU prior to transplant was 82%

**Table IV-14. Expected U.S. 1 Year Graft Survival Rates -- Liver Transplants Stratified by Recipient Age, Diagnosis, Status at Time of Transplant, and Primary or Repeat Transplant**

| Age | Diagnosis | Not Hospitalized | | Hospitalized | | In ICU | |
|---|---|---|---|---|---|---|---|
| | | Primary | Repeat | Primary | Repeat | Primary | Repeat |
| 5 | Acute Hepatic Necrosis | 83.7 | 75.7 | 80.9 | 71.9 | 78.4 | 68.8 |
| | Cholestatic/Biliary Cirrhosis | 87.8 | 81.4 | 85.6 | 78.3 | 83.7 | 75.7 |
| | Cirrhosis | 85.4 | 78.0 | 82.8 | 74.5 | 80.5 | 71.5 |
| | Malignancy | 77.9 | 68.2 | 74.4 | 63.9 | 71.5 | 60.3 |
| | Metabolic Disease | 85.4 | 78.0 | 82.8 | 74.5 | 80.5 | 71.5 |
| | Miscellaneous Disease | 83.5 | 75.5 | 80.7 | 71.7 | 78.2 | 68.6 |
| 25 | Acute Hepatic Necrosis | 85.5 | 78.2 | 82.9 | 74.7 | 80.7 | 71.8 |
| | Cholestatic/Biliary Cirrhosis | 89.3 | 83.5 | 87.3 | 80.6 | 85.5 | 78.2 |
| | Cirrhosis | 87.0 | 80.3 | 84.7 | 77.1 | 82.7 | 74.3 |
| | Malignancy | 80.3 | 71.2 | 77.0 | 67.1 | 74.3 | 63.7 |
| | Metabolic Disease | 87.0 | 80.3 | 84.7 | 77.1 | 82.7 | 74.3 |
| | Miscellaneous Disease | 85.4 | 78.0 | 82.8 | 74.5 | 80.5 | 71.5 |
| 40 | Acute Hepatic Necrosis | 84.9 | 77.3 | 82.2 | 73.8 | 79.9 | 70.8 |
| | Cholestatic/Biliary Cirrhosis | 88.8 | 82.8 | 86.7 | 79.9 | 84.9 | 77.3 |
| | Cirrhosis | 86.5 | 79.5 | 84.1 | 76.2 | 81.9 | 73.4 |
| | Malignancy | 79.5 | 70.1 | 76.1 | 66.0 | 73.3 | 62.5 |
| | Metabolic Disease | 86.5 | 79.5 | 84.1 | 76.2 | 81.9 | 73.4 |
| | Miscellaneous Disease | 84.7 | 77.1 | 82.1 | 73.6 | 79.8 | 70.5 |
| 50 | Acute Hepatic Necrosis | 83.5 | 75.4 | 80.6 | 71.7 | 78.2 | 68.5 |
| | Cholestatic/Biliary Cirrhosis | 87.7 | 81.2 | 85.4 | 78.1 | 83.5 | 75.4 |
| | Cirrhosis | 85.2 | 77.7 | 82.6 | 74.2 | 80.3 | 71.2 |
| | Malignancy | 77.7 | 67.9 | 74.2 | 63.5 | 71.2 | 60.0 |
| | Metabolic Disease | 85.2 | 77.7 | 82.6 | 74.2 | 80.3 | 71.2 |
| | Miscellaneous Disease | 83.3 | 75.2 | 80.5 | 71.4 | 78.0 | 68.3 |
| 60 | Acute Hepatic Necrosis | 81.1 | 72.2 | 77.9 | 68.2 | 75.2 | 64.8 |
| | Cholestatic/Biliary Cirrhosis | 85.8 | 78.5 | 83.3 | 75.1 | 81.1 | 72.2 |
| | Cirrhosis | 83.0 | 74.7 | 80.1 | 70.9 | 77.6 | 67.7 |
| | Malignancy | 74.7 | 64.2 | 70.9 | 59.6 | 67.7 | 56.0 |
| | Metabolic Disease | 83.0 | 74.7 | 80.1 | 70.9 | 77.6 | 67.7 |
| | Miscellaneous Disease | 80.9 | 72.0 | 77.7 | 67.9 | 75.0 | 64.6 |

**Table IV-15. Expected U.S. 1 Year Patient Survival Rates -- Liver Transplants Stratified by Recipient Age, Diagnosis, Status at Time of Transplant, and Primary or Repeat Transplant**

| Age | Diagnosis | Not Hospitalized | | Hospitalized | | In ICU | |
|---|---|---|---|---|---|---|---|
| | | Primary | Repeat | Primary | Repeat | Primary | Repeat |
| 5 | Acute Hepatic Necrosis | 91.2 | 83.9 | 88.9 | 80.1 | 86.9 | 77.0 |
| | Cholestatic/Biliary Cirrhosis | 94.7 | 90.0 | 93.2 | 87.4 | 92.0 | 85.3 |
| | Cirrhosis | 92.3 | 85.7 | 90.2 | 82.3 | 88.4 | 79.4 |
| | Malignancy | 85.7 | 75.1 | 82.2 | 70.0 | 79.4 | 66.0 |
| | Metabolic Disease | 92.3 | 85.7 | 90.2 | 82.3 | 88.4 | 79.4 |
| | Miscellaneous Disease | 91.4 | 84.3 | 89.2 | 80.6 | 87.2 | 77.5 |
| 25 | Acute Hepatic Necrosis | 91.8 | 85.0 | 89.7 | 81.4 | 87.8 | 78.5 |
| | Cholestatic/Biliary Cirrhosis | 95.1 | 90.7 | 93.7 | 88.3 | 92.6 | 86.3 |
| | Cirrhosis | 92.8 | 86.7 | 90.9 | 83.5 | 89.3 | 80.7 |
| | Malignancy | 86.7 | 76.7 | 83.4 | 71.7 | 80.7 | 67.8 |
| | Metabolic Disease | 92.8 | 86.7 | 90.9 | 83.5 | 89.3 | 80.7 |
| | Miscellaneous Disease | 92.0 | 85.4 | 89.9 | 81.8 | 88.1 | 78.9 |
| 40 | Acute Hepatic Necrosis | 90.6 | 82.9 | 88.1 | 78.9 | 86.0 | 75.7 |
| | Cholestatic/Biliary Cirrhosis | 94.3 | 89.3 | 92.8 | 86.6 | 91.4 | 84.3 |
| | Cirrhosis | 91.7 | 84.8 | 89.5 | 81.2 | 87.7 | 78.2 |
| | Malignancy | 84.8 | 73.7 | 81.1 | 68.4 | 78.1 | 64.3 |
| | Metabolic Disease | 91.7 | 84.8 | 89.5 | 81.2 | 87.7 | 78.2 |
| | Miscellaneous Disease | 90.8 | 83.3 | 88.4 | 79.4 | 86.4 | 76.2 |
| 50 | Acute Hepatic Necrosis | 88.6 | 79.7 | 85.7 | 75.2 | 83.3 | 71.6 |
| | Cholestatic/Biliary Cirrhosis | 93.1 | 87.1 | 91.2 | 84.0 | 89.6 | 81.3 |
| | Cirrhosis | 90.0 | 81.9 | 87.4 | 77.7 | 85.2 | 74.4 |
| | Malignancy | 81.8 | 69.4 | 77.7 | 63.7 | 74.3 | 59.3 |
| | Metabolic Disease | 90.0 | 81.9 | 87.4 | 77.7 | 85.2 | 74.4 |
| | Miscellaneous Disease | 88.9 | 80.1 | 86.1 | 75.7 | 83.7 | 72.2 |
| 60 | Acute Hepatic Necrosis | 85.3 | 74.5 | 81.8 | 69.3 | 78.8 | 65.3 |
| | Cholestatic/Biliary Cirrhosis | 90.9 | 83.5 | 88.5 | 79.6 | 86.5 | 76.4 |
| | Cirrhosis | 87.0 | 77.1 | 83.8 | 72.2 | 81.1 | 68.4 |
| | Malignancy | 77.1 | 62.9 | 72.2 | 56.7 | 68.3 | 52.1 |
| | Metabolic Disease | 87.0 | 77.1 | 83.8 | 72.2 | 81.1 | 68.4 |
| | Miscellaneous Disease | 85.6 | 75.1 | 82.2 | 69.9 | 79.3 | 65.9 |

## J. SUMMARY

### Study Period

The 1997 Report was based on 16,658 liver transplants performed in 14,607 patients between January 1, 1988, and April 30, 1994, from 103 transplant programs in the United States. In order to assess changes within transplant programs over time, the data were divided into 2 eras. The first era included transplants performed from January 1, 1988, through April 30, 1992; the second era covered the two year time period from May 1, 1992, through April 30, 1994.

### Survival Rates

Survival rates were computed at 3 months, 1 year, and 3 years, both nationally and for each transplant program. Three year survival was determined in two ways: (1) conditional 3 year survival (i.e., survival at 3 years for those who survived at least 1 year post-transplant), and (2) unconditional 3 year survival. The emphasis on long term survival in this chapter is on the conditional 3-year survival rates because the conditional 3-year analysis provides an assessment of characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

The national graft and patient survival rates and completeness of follow-up at 3 months, 1 year, and conditional 3 years are shown in Tables IV-1 and IV-2. The percent of programs with graft and patient follow-up data at 1 year was more than 98%; at conditional 3 years the percent of programs with follow-up data was greater than 96%.

There was a marked increase in both the number of liver transplants and in the actual graft and patient survival rates from Era 1 to Era 2. As demonstrated in Table IV-16, graft survival rates increased 6% at 3 months and 7% at 1 year in Era 2 from Era 1. Patient survival rates increased 4% at 3 months and 5% at 1 year during the study period.

For the majority of transplant programs, the difference between actual and expected survival rates was not statistically significant, especially in the long term (See Figures IV-1 and IV-3). In general, large differences (either higher or lower) were nearly always found among programs that reported relatively few transplants (see Figure IV-2). Therefore, when evaluating survival rates for a program, it is also important to consider the number of transplants performed there.

### Differences Between Short Term and Long Term Characteristics

The 1997 Report includes an extensive list of characteristics that have a significant impact on both short and long term graft and patient survival.

Characteristics with the strongest *positive* impact on *short term survival* were:

- Recipient had cholestatic disease/biliary cirrhosis
- Year of transplant was after 1990

Characteristics with the strongest *negative* impact on *short term survival* were:

- Donor was Black or Hispanic
- Donor and recipient blood types were incompatible
- Recipient received one or more previous transplants
- Recipient was Asian
- Recipient received a reduced or split liver
- Recipient was on life support prior to transplant
- Recipient's most recent serum creatinine prior to transplant was >2 mg/dl

Characteristics with the strongest *positive* impact on *long term survival* were:

- Donor cause of death was cardiovascular accident (CVA)
- Recipient was female
- Recipient had acute hepatic necrosis, cholestatic disease/biliary cirrhosis, metabolic disease or miscellaneous disease

Characteristics with the strongest *negative* impact on *long term survival* were:

- Donor was female
- Recipient received one or more previous transplants
- Recipient was 1 year of age or younger
- Recipient received a reduced or split liver
- Recipient had malignant neoplasms

**Table IV-16. Comparison of 3 Month and 1 Year Actual Survival Rates Between Eras**

| | 3 Months | | 1 Year | |
|---|---|---|---|---|
| | Era 1 | Era 2 | Era 1 | Era 2 |
| Graft Survival (%) | 75.5% | 81.1% | 67.3% | 74.1% |
| Average No. Transplants/Month | 197 | 267 | 197 | 267 |
| Patient Survival (%) | 83.7% | 87.8% | 76.9% | 82.2% |
| Average No. Patients/Month | 171 | 244 | 171 | 244 |

## K. FINAL WORDS

The purpose of this report is to provide updated information on survival outcomes both nationally and at specific transplant programs, and to enhance the awareness of program performance in the U.S. However, the assessment of a transplant program should not be based solely on the survival rates provided in this report. Some of the other important factors to consider are the experience of the transplant team, support personnel, the cost of the procedure, and the quality and location of post-transplant services.

# V. PANCREAS CHAPTER

# V. PANCREAS TRANSPLANT SURVIVAL RATES

*For the Summary of this chapter, see page 86. For definitions of any terms used here, please refer to the User's Guide in the Pancreas volume.*

## A. INTRODUCTION

This report of pancreas transplant survival rates is based upon verified Scientific Registry data for 3,222 transplants involving 3,142 patients from 96 pancreas transplant programs in the United States. Each program reporting at least one pancreas or combined kidney-pancreas transplant between January 1, 1988, and April 30, 1994, was included. Multi-organ transplants other than combined kidney-pancreas procedures were excluded.

Short term survival is defined as survival at 3 months and 1 year post-transplant. Short term survival rates are based on all transplants in the study for which there are follow-up data.

Long term survival is defined in two ways:

- unconditional survival at 3 years post-transplant, and
- survival at 3 years post-transplant for those who survived at least 1 year, referred to as **conditional 3 year survival**.

The long term survival rates are based on all transplants between January 1, 1988, and April 30, 1992, for which there are follow-up data. This cohort was chosen to ensure that the maximum number of transplants with follow-up data was used to determine long term survival rates. Please note that the emphasis on long term survival in this report is on the *conditional* 3-year survival rates. This is because the conditional 3-year analysis provides an assessment of characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

## B. COMPLETENESS OF FOLLOW-UP DATA AND OVERALL GRAFT AND PATIENT SURVIVAL RATES

For graft survival, completeness of follow-up data and overall actual survival rates at each time point are shown in Table V-1; patient survival data are shown in Table V-2.

Patient (graft) follow-up data were considered complete when:

- the patient was alive (pancreas was functioning) and the duration of survival (function) was equal to or exceeded the specified time after transplant (i.e., 3 months, 1 or 3 years), or
- the patient died (pancreas failed) and a valid date of death (failure) was reported.

The percentages of complete follow-up data ranged from a low of 93.9% for the conditional 3 year time point to a high of 99.9% for the 3 month time point. Patient survival rates are better than graft survival rates at all time points because other medical therapy is available for patients whose grafts fail.

Overall survival rates also are presented in the tables. If a graft had incomplete follow-up data, the observation was weighted to account for the time during which the graft was known to be functioning. Therefore, the actual graft survival rate reflects the weighted proportion of grafts functioning at the specified time interval. Patient survival rates were computed in a similar way (see the *Technical Methods* chapter of the *Executive Summary*).

In the calculation of graft survival rates, death with a functioning graft was treated differently depending upon the time interval. For short term survival (3 months, 1 year), grafts were considered to have failed at the time of death because it is reasonable to assume that deaths occurring shortly after a transplant are likely to be related to graft dysfunction. For long term survival, because it is more likely that death might not be related to graft failure, if a patient died with a functioning graft more than 1 year after a transplant, the graft was treated as a censored observation at the time of death. In other words, it was treated as if the graft still functioned but further follow-up data were unavailable. The graft then was weighted for the proportion of time in the period that the graft was functioning. (see the *Technical Methods* chapter of the *Executive Summary for a complete description of weighting.)*

In the cohort of transplants (1/1/88 - 4/30/92) used to compute conditional 3 year survival rates, patients (grafts) who did not survive to 1 year after transplant were excluded from the analyses. Therefore, the total number of patients (grafts) for the conditional 3 year analysis was less than that for the 3 month and 1 year analyses. Further, the number of patients is greater than the number of grafts because more grafts failed than patients died within the first year post-transplant.

Please note that the conditional 3 year graft and patient survival rates in Tables V-1 and V-2 may be higher than the 1 year graft survival rates. This is possible because the conditional 3 year survival rates should be interpreted as the 3 year survival rate for patients (grafts) who (which) survived at least 1 year post-transplant.

For example: Program A performed a total of five transplants between 1/1/88 and 4/30/92. Two of the pancreata failed prior to 1 year post-transplant and the remaining three pancreata survived to 3 years after transplant. In this example, Program A has a 1 year graft survival rate of 60% (3 out of 5 pancreata were functioning at 1 year post-transplant). However, the conditional 3 year survival rate for Program A is 100% because all three pancreata that were functioning at 1 year after transplant also were functioning at 3 years post-transplant. The same calculations are used for patient survival. See the *Technical Methods* chapter of the *Executive Summary* for more specific definitions of follow-up data and the calculations for actual graft and patient survival.

## Overall Graft and Patient Survival Rates by Era

In this report, short term survival also is reported by era. Separate eras were used to determine whether there were any improvements over time in the short term survival rates. Era 1 is defined as all transplants occurring between January 1, 1988, and April 30, 1992; Era 2 includes all transplants occurring between May 1, 1992, and April 30, 1994. The overall graft and patient survival rates by era are presented in the last two columns of Table V-1 and Table V-2, respectively. The results demonstrate improvement in both graft and patient survival rates over time.

**Table V-1. Completeness of Graft Follow-Up Data and Actual Survival Rates for Pancreas Transplants**

| Time | Cohort | Number of Transplants | Percent with Follow-Up Data | Graft Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 3 Months | 1/1/88 - 4/30/94 | 3,222 | 99.9 | 83.6 | 82.4 | 85.2 |
| 1 Year | 1/1/88 - 4/30/94 | 3,222 | 99.3 | 73.5 | 71.9 | 75.7 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 1,310 | 93.9 | 91.3* | 91.3* | N/A* |

**Table V-2. Completeness of Patient Follow-Up Data and Actual Survival Rates for Pancreas Transplants**

| Time | Cohort | Number of Patients | Percent with Follow-Up Data | Patient Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 3 Months | 1/1/88 - 4/30/94 | 3,142 | 99.2 | 96.1 | 94.9 | 97.5 |
| 1 Year | 1/1/88 - 4/30/94 | 3,142 | 96.5 | 91.1 | 90.4 | 92.2 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 1,595 | 94.4 | 92.3* | 92.3* | N/A* |

* The cohort used to determine the overall conditional 3 year survival rate is the same as the Era 1 cohort. Therefore, the overall conditional 3 year survival rates are identical to the conditional 3 year survival rates for Era 1. There is no conditional 3 year survival rate calculated for Era 2 due to insufficient follow-up data on patients who received transplants in Era 2.

## C. GRAFT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

For each transplant program, actual and expected survival rates were calculated at 3 months, 1 year, and 3 years conditional on survival at 1 year. Survival rates at each time point were determined using a specific cohort of transplants (shown in Tables V-1 and V-2 on the previous page). Expected survival rates were determined for each transplant program based on its specific patient and donor characteristics. These expected outcomes were statistically adjusted for many important prognostic variables, or covariates, that were used in the survival analysis. In other words, they take into account the many different characteristics that affect survival. For example: *if Program A transplanted many more "high risk" recipients than Program B, then Program A would have a lower expected survival rate than Program B.*

If a program's *actual* survival rate was *greater* than its expected survival rate, this means that the program's actual results were higher than the national results for transplants *with the same donor and recipient characteristics*. If a program's *actual* survival rate was *less than* its expected survival rate, this means that the program's actual results were lower than the national results for transplants *with the same donor and recipient characteristics. The difference between the actual and expected rate may have occurred by chance and, therefore, may not be statistically significant.* Furthermore, even a statistically significant difference, one that most likely did not occur by chance, may not be clinically significant (i.e., medically important). A formal description of the methods used to determine actual and expected survival rates appears in the *Technical Methods* chapter of the *Executive Summary*.

Table V-3 shows the percentages of pancreas transplant programs by graft survival rates, both for actual and expected survival. The majority of the transplant programs had actual survival rates greater than 60% at all time points. The short term survival rates showed a greater variation among programs than the long term survival rates. At 3 months, 36.4% of programs had actual survival rates greater than 90% At 1 year, this fell to 18.8%. However, the percentage increased to 63.2% for the conditional 3 year survival rates. The distribution of the expected survival rates shows a similar trend. The results indicate that there are more programs with high survival rates (>90%) at the conditional 3 year time point than there are at the 1 year time point. *This is because the most critical period of time for graft survival is the first year post-transplant.* Those who survive the first year are very likely to survive 3 years post-transplant.

The percentages of programs by short term graft survival rates and eras, both for actual and expected survival, are summarized in Table V-4. The results demonstrate a substantial improvement in graft survival over time because a greater percentage of programs had actual survival rates higher than 90% in Era 2. Expected survival rates in Era 2 also were higher than in Era 1.

**Table V-3. Percentages of Pancreas Transplant Programs by Graft Survival Rates**

| Graft Survival Rates (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 3 Months (n= 96) | 1 Year (n=96) | Cond. 3 Yrs (n=65) | 3 Months (n=96) | 1 Year (n=96) | Cond. 3 Yrs (n=65) |
| 0-40 | 7.3 | 9.4 | 1.5 | 0.0 | 0.0 | 0.0 |
| >40-60 | 6.3 | 14.6 | 1.5 | 0.0 | 1.0 | 0.0 |
| >60-80 | 25.0 | 42.6 | 12.3 | 7.3 | 84.4 | 4.6 |
| >80-90 | 25.0 | 14.6 | 21.5 | 92.7 | 14.6 | 12.3 |
| >90-100 | 36.4 | 18.8 | 63.2 | 0.0 | 0.0 | 83.1 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Table V-4. Percentages of Pancreas Transplant Programs by Graft Survival Rates and Era**

| Graft Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Era 1 (n=70) | Era 2 (n=86) | Era 1 (n=70) | Era 2 (n=86) | Era 1 (n=70) | Era 2 (n=86) | Era 1 (n=70) | Era 2 (n=86) |
| 0-40 | 10.0 | 4.7 | 14.3 | 9.3 | 0.0 | 0.0 | 0.0 | 0.0 |
| >40-60 | 10.0 | 5.8 | 15.7 | 9.3 | 0.0 | 0.0 | 1.4 | 1.2 |
| >60-80 | 28.6 | 22.1 | 45.7 | 36.0 | 14.3 | 1.2 | 87.1 | 67.4 |
| >80-90 | 24.3 | 27.9 | 14.3 | 19.8 | 85.7 | 98.8 | 11.5 | 31.4 |
| >90-100 | 27.1 | 39.5 | 10.0 | 25.6 | 0.0 | 0.0 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Differences in Actual and Expected Survival Rates**

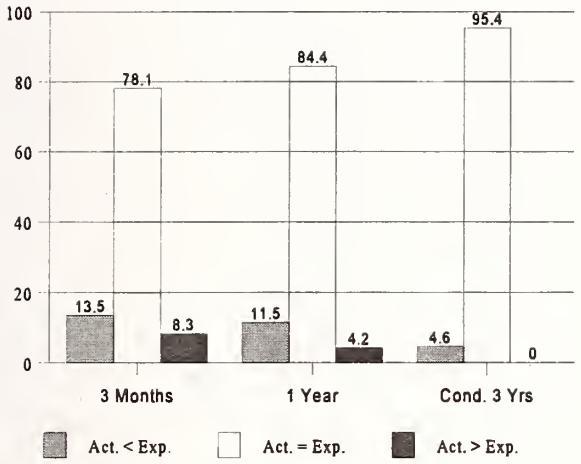
For most programs, the difference between the actual survival rate and the expected survival rate was not statistically significant. Figure V-1 shows the percentages of programs whose actual graft survival rates were either above, equal to, or below expected graft survival rates at three time points. Programs with actual survival rates that were not significantly different from expected rates are shown in the actual survival equals expected survival group. Actual survival rates shown in the figure to be greater than or less than expected survival rates were statistically significant. Overall, there were more programs that fell significantly below expected results than above expected results. However, for the majority of the transplant programs, the difference in actual and expected graft survival was not statistically significant.

At all time points, the larger differences in actual and expected rates were nearly always seen in programs that reported relatively few transplants during the period. This occurs because programs that do not perform many transplants tend to have highly variable outcomes. To illustrate this, Figure V-2 shows a scatter plot of the average number of transplants per year (transplant volume) versus the difference in 1 year actual and expected graft survival. Nearly all differences greater than 10% (either positive or negative) are found among transplant programs performing fewer than 12 pancreas transplants per year. Please note that actual survival rates which differ from expected survival rates are not always statistically significant and even statistically significant differences may not be clinically significant.

## D. PATIENT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

The percentages of programs by patient survival rates for both actual and expected survival are shown in Table V-5; the percentages of programs by survival rates and eras are shown in Table V-6. As with graft survival, the outcomes in Era 2 were better than in Era 1.

**Figure V-1. Percentages of Pancreas Transplant Programs with Actual Graft Survival Rates Above, Below, or Equal to Expected Survival Rates. ***




*Actual survival rates above or below expected survival rates are statistically significant.

**Figure V-2. Pancreas Transplant Volume vs Difference in Actual and Expected 1 Year Graft Survival Rates.**

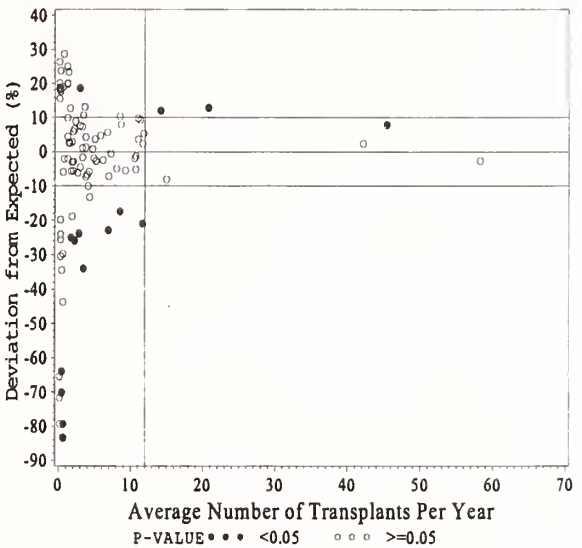



**Table V-5. Percentages of Pancreas Transplant Programs by Patient Survival Rates**

| Patient Survival Rate (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 3 Months (n= 96) | 1 Year (n=96) | Cond. 3 Yrs (n=69) | 3 Months (n=96) | 1 Year (n=96) | Cond. 3 Yrs (n=69) |
| 0-70 | 2.1 | 5.1 | 5.8 | 0.0 | 0.0 | 0.0 |
| >70-80 | 3.1 | 6.3 | 1.4 | 0.0 | 0.0 | 0.0 |
| >80-90 | 6.3 | 25.0 | 23.2 | 0.0 | 20.8 | 11.6 |
| >90-95 | 13.5 | 16.7 | 29.0 | 18.8 | 79.2 | 84.1 |
| >95-100 | 75.0 | 46.9 | 40.6 | 81.2 | 0.0 | 4.3 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

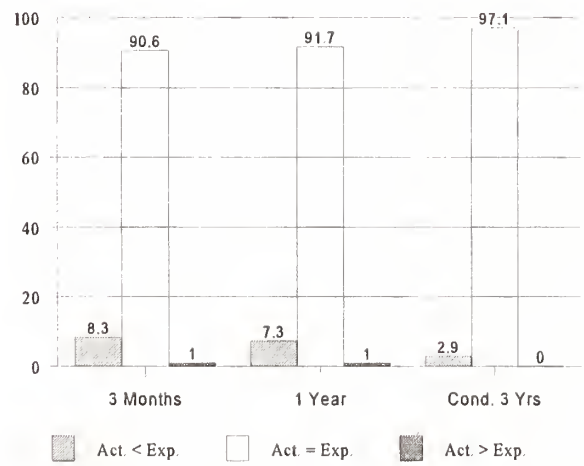
**Table V-6. Percentages of Pancreas Transplant Programs by Patient Survival Rates and Era**

| Patient Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Era 1 (n=70) | Era 2 (n=86) | Era 1 (n=70) | Era 2 (n=86) | Era 1 (n=70) | Era 2 (n=86) | Era 1 (n=70) | Era 2 (n=86) |
| 0-70 | 8.6 | 0.0 | 11.4 | 3.5 | 0.0 | 0.0 | 0.0 | 0.0 |
| >70-80 | 2.9 | 1.2 | 11.4 | 4.7 | 0.0 | 0.0 | 0.0 | 0.0 |
| >80-90 | 14.3 | 5.8 | 22.9 | 18.6 | 0.0 | 0.0 | 41.4 | 8.1 |
| >90-95 | 17.1 | 4.7 | 20.0 | 18.6 | 54.3 | 1.2 | 58.6 | 91.9 |
| >95-100 | 57.1 | 88.3 | 34.3 | 54.6 | 45.7 | 98.8 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Differences in Actual and Expected Survival Rates**

The percentage of programs with actual patient survival rates significantly above their expected rates was only 1% for short term survival, and no programs had actual rates significantly greater than expected for long term survival (see Figure V-3). As with graft survival, there were more programs that fell significantly below expected results than above expected results. However, for the majority of transplant programs, the difference in actual and expected patient survival was not statistically significant and varied little over time.

**Figure V-3. Percentages of Pancreas Transplant Programs with Actual Patient Survival Rates Above, Below, or Equal to Expected Survival Rates. ***




*Actual survival rates above or below expected survival rates are statistically significant.

## E. NATIONAL DISTRIBUTION OF DONOR AND RECIPIENT CHARACTERISTICS

The national distribution of donor and recipient characteristics for pancreas transplants, presented in percentages, is shown in Table V-7. Each of these donor and recipient characteristics was included in the analyses for graft or patient survival, and those that proved to be significant were used to determine an expected survival rate for each transplant.

The majority of pancreata transplanted were recovered from white male donors under the age 30. Most recipients were under the age of 18 at the onset of their diabetes. Of the 3,222 transplants, 87% of the patients received a kidney at the same time, and less than 4% were repeat pancreas transplants.

**Table V-7. National Donor and Recipient Characteristics in Pancreas Transplants: Percentages by Era and Overall**

| Characteristics | | ERA 1 5/92-4/94 N=1,826 | ERA 2 5/92-4/94 N=1,396 | OVERALL 1/88-4/94 N=3,222 |
|---|---|---|---|---|
| **Donor Age** | 0-17 | 20.8 | 24.9 | 22.6 |
| | 18-29 | 40.6 | 37.5 | 39.3 |
| | 30-39 | 19.9 | 17.6 | 18.9 |
| | 40-49 | 13.9 | 14.0 | 14.0 |
| | 50+ | 4.8 | 6.0 | 5.3 |
| **Donor Race** | White | 88.7 | 83.9 | 86.6 |
| | Black | 7.0 | 9.7 | 8.2 |
| | Hispanic | 3.4 | 4.9 | 4.1 |
| | Asian | 0.5 | 1.0 | 0.7 |
| | Other | 0.4 | 0.4 | 0.4 |
| **Recipient Age** | 0-17 | 0.1 | 0.1 | 0.1 |
| | 18-29 | 21.7 | 16.1 | 19.3 |
| | 30-39 | 49.3 | 51.2 | 50.2 |
| | 40-49 | 25.8 | 28.7 | 27.1 |
| | 50+ | 3.0 | 3.8 | 3.3 |
| **Recipient Race** | White | 93.5 | 89.3 | 91.7 |
| | Black | 3.8 | 6.0 | 4.7 |
| | Hispanic | 1.8 | 2.2 | 2.0 |
| | Asian | 0.3 | 0.3 | 0.3 |
| | Other | 0.7 | 2.1 | 1.3 |
| | Not Reported | 0.0 | 0.1 | 0.0 |
| **Age at Diabetes Onset** | 0-9 | 35.0 | 30.1 | 32.9 |
| | 10-17 | 44.6 | 44.8 | 44.7 |
| | 18-30 | 18.1 | 20.1 | 19.0 |
| | 31+ | 2.0 | 1.6 | 1.8 |
| | Not Reported | 0.3 | 3.4 | 1.6 |

| | | ERA 1 | ERA 2 | OVERALL |
|---|---|---|---|---|
| **Years Between Diabetes Onset and Transplant** | 1-9 | 1.1 | 1.1 | 1.1 |
| | 10-19 | 28.5 | 25.5 | 27.2 |
| | 20-29 | 54.1 | 52.9 | 53.5 |
| | 30-39 | 14.7 | 15.8 | 15.2 |
| | 40+ | 1.3 | 1.3 | 1.3 |
| | Not Reported | 0.3 | 3.4 | 1.6 |
| **Previous Pancreas Transplant** | No | 95.9 | 96.3 | 96.1 |
| | Yes | 4.1 | 3.7 | 3.9 |
| **Transplant Procedure*** | SKP | 86.1 | 88.2 | 87.0 |
| | PAK | 6.5 | 6.1 | 6.3 |
| | PTA | 7.3 | 5.7 | 6.6 |
| **Cold Ischemic Time (Hours)** | 0-8 | 24.4 | 14.0 | 19.9 |
| | 9-13 | 29.5 | 33.1 | 31.0 |
| | 14-18 | 24.9 | 29.6 | 26.9 |
| | 19-23 | 14.6 | 17.3 | 15.8 |
| | 24+ | 5.1 | 5.0 | 5.1 |
| | Not Reported | 1.5 | 1.0 | 1.3 |
| **Level of Mismatch** | 0 | 1.0 | 1.1 | 1.1 |
| | 1 | 2.0 | 2.7 | 2.3 |
| | 2 | 7.6 | 9.1 | 8.2 |
| | 3 | 18.4 | 20.2 | 19.2 |
| | 4 | 28.4 | 29.7 | 29.0 |
| | 5 | 28.5 | 24.3 | 26.7 |
| | 6 | 12.4 | 11.6 | 12.0 |
| | Not Reported | 1.8 | 1.2 | 1.5 |
| **Year of Transplant** | 1988 | 12.7 | 0.0 | 7.2 |
| | 1989 | 21.5 | 0.0 | 12.2 |
| | 1990 | 28.3 | 0.0 | 16.0 |
| | 1991 | 28.6 | 0.0 | 16.2 |
| | 1992 | 8.9 | 27.7 | 17.0 |
| | 1993-1994 | 0.0 | 72.3 | 31.3 |

* Procedure types: SKP-Simultaneous Kidney/Pancreas, PAK-Pancreas after Kidney, PTA-Pancreas transplanted alone.

Donor and Recipient Trends

National donor and recipient characteristics changed between Era 1 and Era 2. The percentage of minority donors and recipients increased from 11.3% to 16.1% and from 6.5% to 10.7% respectively. There was a slightly higher percentage of simultaneous kidney-pancreas transplants in Era 2. Also, more transplants had longer cold ischemic times (> 8 hours).

## F. SHORT TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

To determine the expected survival for each transplant or patient, separate analyses were performed for graft and patient survival at three time points. (The analyses were performed using logistic regression, see the *Technical Methods* chapter in the *Executive Summary.*) The analyses also identified donor and recipient characteristics that had a significant impact on survival outcomes. For each *characteristic* (e.g., race, gender) considered in the analyses, a *reference group* was chosen (e.g., White, male) with which the other groups were compared. As a general rule, the largest group or the mean of the characteristic (e.g., mean recipient age=36) is often used as the reference group.

The following served as the characteristics and reference groups for ***short term graft*** survival:

- Mean Donor Age -- 28 years
- Previous Pancreas Transplant -- no
- Mean Recipient Age -- 36 years
- Procedure Type -- simultaneous kidney-pancreas
- Transplant Year -- 1988

The following served as the characteristics and reference groups for ***short term patient*** survival:

- Mean Donor Age -- 28 years
- Mean Cold Ischemic Time -- 14 hours
- Mean Recipient Age -- 36 years
- Recipient Race -- non-Black
- Transplant Year -- 1988

The relative impact of each donor and recipient characteristic on short term graft and patient survival outcomes is listed in Table V-8. For each characteristic, the ***odds ratio*** is the odds of patient death (graft failure) as compared to the reference group, after adjusting for the effects of all other donor and recipient characteristics. An *odds ratio of less than 1* indicates that the characteristic was associated with a *reduced odds* of patient death or graft failure relative to the reference group. An odds ratio of *greater than 1* indicates that the characteristic was associated with an *increased odds* of death relative to the reference group. The corresponding p-value measures the significance of the odds ratio. A p-value less than 0.05 indicates statistical significance and means that there is less than a 5% probability that such difference is due to chance alone. The smaller the p-value, the greater the statistical significance and the less likely the difference is due to chance alone.

Examples

In Table V-8, the odds ratio of graft failure within 1 year after a repeat transplant versus a first, or primary, transplant was 1.85. This means that, after adjusting for all of the other donor and recipient characteristics, the odds of graft failure within 1 year was 85% greater for repeat transplants than for primary transplants ((1.85-1)x100%=85%). As another example, the odds ratio of graft failure within 1 year post-transplant for a recipient who received a pancreas alone versus a simultaneous kidney-pancreas was 2.91. After adjusting for the effects of both donor and recipient characteristics, the odds of graft failure within 1 year for a patient who received a pancreas alone was 191% higher than that for a patient who received a simultaneous kidney-pancreas ((2.91-1)x100%=191%).

The estimated odds ratios for continuous variables (i.e., variables with many possible values) such as cold ischemic time, and donor and recipient ages are less easily interpreted. For these variables, the estimated odds is determined for every 1 or 10 unit increase or decrease from the mean (reference group) of the variable. For example, in Table V-8, the estimated odds of 1 year graft failure for a pancreas from a 38 year old donor compared to the mean of 28 years is 1.22. This means that, after adjusting for the effects of all other characteristics, the odds of graft failure was estimated to increase by 22% for the first 10 year increase from the mean donor age.

An increase of 20 years from the mean (i.e., the donor age is $\underline{28+20=48}$) would result in a 48% increase in the odds of graft failure.
Mathematically, this 48% was calculated as follows:

$$\text{Odds ratio} = \exp^{\left(\frac{20}{10}\times 0.1957\right)} = 1.48$$

where the 20 year increase is equivalent to 2 per 10 year difference, and 0.1957 corresponds to the coefficient of donor age per 10 year difference (see Table V-11 for coefficients). Therefore, the increase in the odds of graft failure is (1.48-1)×100%=48%. For some variables such as recipient age, it is necessary to add a quadratic term. For more details on calculating odds ratios for continuous variables, refer to the section on *Odds Ratios* in the *Technical Methods* chapter of the *Executive Summary*.

**Table V-8. Impact of Donor and Recipient Characteristics on Short Term Graft and Patient Survival--Pancreas Transplants**

| Short Term Characteristics | Graft Survival [1] | | | | Patient Survival [1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Odds Ratio | P-value [2] | Odds Ratio | P-value [2] | Odds Ratio | P-value [2] | Odds Ratio | P-value [2] |
| **Donor Age 38 vs 28** [3,5] | 1.239 | <0.001 | 1.216 | <0.001 | 1.122 | 0.162 | 1.085 | 0.129 |
| **Cold Ischemic Time (hours) 15 vs 14** [3] | --- | n.d. | --- | n.d. | 0.969 | 0.061 | 0.986 | 0.197 |
| **Previous Pancreas Transplant -- Yes vs No** | 1.118 | 0.645 | 1.851 | 0.004 | --- | n.d. | --- | n.d. |
| **Recipient Age 46 vs 36** [3,4] | 1.022 | 0.808 | 1.147 | 0.066 | 1.026 | 0.846 | 1.360 | 0.001 |
| **Recipient Black vs non-Black** | --- | n.d. | --- | n.d. | 1.696 | 0.143 | 0.933 | 0.822 |
| **Pancreas After Kidney vs Simultaneous Kidney-Pancreas** | 2.115 | <0.001 | 2.421 | <0.001 | --- | n.d. | --- | n.d. |
| **Pancreas Alone vs Simultaneous Kidney-Pancreas** | 1.463 | <0.001 | 2.906 | <0.001 | --- | n.d. | --- | n.d. |
| **TX Year 1989 vs 1988** | 0.630 | 0.025 | 0.830 | 0.316 | 0.832 | 0.615 | 0.798 | 0.409 |
| **TX Year 1990 vs 1988** | 0.756 | 0.147 | 1.149 | 0.428 | 0.941 | 0.858 | 0.969 | 0.900 |
| **TX Year 1991 vs 1988** | 0.513 | 0.001 | 0.679 | 0.031 | 0.705 | 0.333 | 0.578 | 0.045 |
| **TX Year 1992 vs 1988** | 0.552 | 0.003 | 0.653 | 0.018 | 0.676 | 0.279 | 0.730 | 0.230 |
| **TX Year 1993-1994 vs 1988** | 0.545 | 0.001 | 0.725 | 0.050 | 0.347 | 0.003 | 0.589 | 0.032 |

Notes:

[1] In the short term survival analysis, if a patient died with a functioning graft (DWFG), the pancreas was considered to have failed at the time of death.

[2] n.d. denotes p-value not determined due to either (a) using a different reference group, or (b) results not statistically significant, and therefore factor is not included in the analysis.

[3] Odds ratios for continuous covariates (donor and recipient age, and cold ischemic time) do not always have a linear relationship in all models. The odds ratios presented in this table correspond to 1 or 10 unit increases from the mean of each covariate. The mean donor age was 28. The mean cold ischemic time was 14 hours. The mean recipient age was 36.

[4] Graft model contains a quadratic term.

[5] Patient model contains a quadratic term.

Graft Survival

The factors that had the strongest impact on short term graft survival were procedure type, previous pancreas transplant, donor age, and transplant year. The odds of 1 year graft failure was 191% higher for recipients of a pancreas alone, and 142% higher for a recipient of a pancreas after a kidney than for a recipient who received a simultaneous kidney-pancreas transplant. Patients who had a previous pancreas transplant had an 85% higher odds of 1 year graft failure than patients receiving their first pancreas. Recipients of a pancreas from a 38 year old donor had a 24% higher odds of 3 month graft failure than did a recipient of a pancreas from a 28 year old donor. Patients receiving their graft in 1993 or 1994 had a 45% lower odds of graft failure than did patients receiving their graft in 1988.

Patient Survival

The factors that had the strongest impact on short term patient survival were recipient race, donor age, and transplant year. Black recipients had a 70% higher odds of death at 3 months than did non-Blacks. A 46 year old recipient had a 36% higher odds of death at 1 year compared to a 36 year old recipient. A patient who receives a pancreas from a 38 year old donor has a 9% higher odds of death at 1 year than a patient who receives a pancreas from a 28 year old donor. A patient who received a pancreas in 1993 or 1994 had a 65% lower odds of mortality at 3 months than did a patient who received a pancreas in 1988.

## G. LONG TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

In this report, long term survival analyses were developed separately from the short term survival analyses. Because this narrative focuses on conditional 3 year survival (survival at 3 years for grafts or patients surviving at least 1 year post-transplant), only conditional 3 year survival data are presented in this text. Both conditional and unconditional 3 year survival rates are provided in the tables for each transplant program presented in each organ specific volume.

The conditional 3 year survival analyses provide an assessment of the donor and recipient characteristics that are independent of those limited to the first year (e.g., surgical complications). Furthermore, for the long term survival analysis, if a patient died with a functioning graft, the graft was not considered to have failed as it was with short term survival. *This was done because deaths occurring some years after a transplant are less likely to be related to the transplant.*

The impact of each donor and recipient characteristic on graft and patient long term survival is listed in Table V-9.

The following characteristic and reference group was used for ***long term graft*** survival:

- Procedure Type -- simultaneous kidney-pancreas

The following characteristics and reference groups were used for ***long term patient*** survival:

- Mean Donor Age -- 28 years
- Donor Race -- non-Black
- Mean Cold Ischemic Time -- 14 hours
- Mean Years Between Diabetes Onset and Transplant -- 23 years
- Mean Recipient Age -- 36 years

Graft and Patient Survival

The only significant factor in the conditional 3 year graft survival model was procedure type. Patients who received a pancreas after a kidney had a 521% higher odds of graft failure, and patients who received a pancreas alone had a 630% higher odds of graft failure than did patients receiving a simultaneous kidney-pancreas transplant.

Factors that impacted long term patient survival were donor and recipient age, cold ischemic time, years between diabetes onset and transplant, and donor race. Patients who received a pancreas from a black donor had a 77% higher odds of death than a recipients of a non-Black donor pancreas. A 46 year old recipient had a 38% higher odds of death than did a 36 year old recipient. A patient who received a pancreas from a 38 year old donor had a 23% higher odds of death at 3 years than a recipient of a 28 year old donor pancreas.

**Table V-9. Impact of Donor and Recipient Characteristics on Long Term Graft and Patient Survival -- Pancreas Transplants**

| Long Term Characteristics | Graft [1] | | Patient [1] | |
|---|---|---|---|---|
| | Odds Ratio | P-value [2] | Odds Ratio | P-value [2] |
| **Donor Age 38 vs 28** [3] | --- | n.d. | 1.232 | 0.008 |
| **Donor Black vs Non-Black** | --- | n.d. | 1.773 | 0.072 |
| **Cold Ischemic Time (hours) 15 vs 14** [3,4] | --- | n.d. | 0.989 | 0.436 |
| **Recipient Age 46 vs 36** [3,4] | --- | n.d. | 1.376 | 0.065 |
| **Years Between Diabetes Onset and Transplant 24 vs 23** [3] | --- | n.d. | 1.026 | 0.120 |
| **Pancreas After Kidney vs Simultaneous Kidney-Pancreas** | 6.212 | <0.001 | --- | n.d. |
| **Pancreas Alone vs Simultaneous Kidney-Pancreas** | 7.298 | <0.001 | --- | n.d. |

Notes:

[1] In the long term survival analysis, if a patient died with a functioning graft (DWFG), the pancreas was not considered to have failed at the time of death.

[2] n.d. denotes p-value not determined due to either (a) using a different reference group, or (b) results not statistically significant, and therefore factor is not included in the analysis.

[3] Odds ratio for continuous covariates (donor age, cold ischemic time, recipient age, and years between diabetes onset and transplant) do not all have a linear relationship. The odds ratios presented in this table correspond to 1 or 10 unit increases from the mean of each covariate. The mean donor age was 28. The means cold ischemic time was 14 hours. The mean recipient age was 36, the mean number of years between diabetes onset and transplant was 23 years.

[4] Model contains a quadratic term.

## H. COMPARISON BETWEEN SHORT TERM AND LONG TERM CHARACTERISTICS

The factor that had the greatest impact on short term graft survival, procedure type, had an even greater impact on long term graft survival. The odds of graft failure for receiving a pancreas after a kidney as opposed to a simultaneous kidney-pancreas transplant went from 115% at 3 months to 142% at 1 year to 521% in the conditional 3 year analysis. The odds of graft failure for a pancreas alone versus a simultaneous kidney-pancreas transplant increased from 46% at 3 months to 630% for long term conditional survival. The remaining factors that impacted short term graft survival did not significantly impact long term graft survival.

Most of the factors that impacted short term patient survival continued to impact long term patient survival. The odds of death for a 10 year increase from the mean for both donor and recipient age increased over time. While the number of years between diabetes onset and transplant did not have a significant impact on short term survival, it did have an impact on long term survival. Race played a factor in both short and long term patient survival. In the short term model Black recipients had a 70% higher odds of death at 3 months than did non-Blacks, and in the long term model a recipient of a pancreas from a Black donor had a 77% higher odds of death than that of a recipient of a non-Black donor pancreas.

## I. STATISTICAL METHODS AND MODELS

***This section provides a brief summary of the statistical methods used to determine survival rates for pancreas transplants, both nationally and at each transplant program. It is <u>not</u> necessary to read this section in order to utilize the rest of the report. For additional statistical details, please see the Technical Methods chapter in the Executive Summary.***

### Model Significance -- $R^2$

The conclusion that there is a "center effect" in pancreas transplantation often is based on the observation that actual survival rates vary considerably among pancreas transplant programs. However, in reality, only part of the variability can be attributed to the quality of the program (the so called "center effect"); the rest can be attributed to the differences in donor and recipient characteristics among transplant programs. The degree to which the variability in actual survival rates can be attributed to the specific donor and recipient characteristics in each analysis appears in Table V-10.In the table, the values in the column labeled $R^2$ estimate the percentage of variability in the actual survival rates that can be attributed to the covariates in each analysis. The higher the percentage, the better the analysis explained the individual program outcomes, based on the characteristics examined. Theoretically, if an analysis contained every covariate that affected survival outcomes, and there were no differences in quality among programs (i.e., no "center effect"), then $R^2$ would equal 100%. In practice, we can never capture every factor that affects outcomes, and it is likely that real differences among programs do exist. This means that any unexplained variation can probably be attributed to a combination of true center effect and covariates not considered in this study. (For details on the $R^2$ calculation, refer to the *Model Significance* section in the *Technical Methods* chapter of the *Executive Summary.* )

The value of $R^2$ estimated from analyses in the 1994 Report was compared to the value of the $R^2$ analyses in the 1997 Report. Note that these analyses are not *directly* comparable since each was used with a different cohort of transplants. Despite the refinements in the 1997 Report, as compared to the 1994 Report, much of the variation in actual survival rates among the 96 transplant programs in the study remains unexplained by the analyses. This suggests that much of the risk involved in transplantation is due to characteristics not described in this report.

**Table V-10. Pancreas Model $R^2$: Comparison of the 1994 and 1997 Reports**

| Outcome | Time Point | Report Year | Number of Covariates | $R^2$ |
|---|---|---|---|---|
| **Graft Model $R^2$** | 3 Months | 1997<br>1994 | 12<br>13 | 33.7<br>29.7 |
| | 1 Year | 1997<br>1994 | 12<br>13 | 34.1<br>36.9 |
| | Conditional 3 Years* | 1997<br>1994 | 3<br>N.A. | 31.0<br>N.A. |
| **Patient Model $R^2$** | 3 Months | 1997<br>1994 | 11<br>9 | 15.6<br>14.1 |
| | 1 Year | 1997<br>1994 | 11<br>9 | 8.3<br>20.7 |
| | Conditional 3 Years* | 1997<br>1994 | 8<br>N.A. | 32.6<br>N.A. |

* Conditional 3 year analysis was not performed in the 1994 report.

**Estimated Coefficients and Standard Errors from the Logistic Regression Models**

Tables V-11 and V-12 list the coefficients and the standard errors of the coefficients at each time point for all of the donor and recipient characteristics used in the logistic regression models. Each coefficient is reported on the logistic scale and represents the $\log_e$ odds of graft failure or the $\log_e$ odds of patient mortality for the corresponding characteristic at the specified time after transplant. The adjusted odds ratio on the probability scale may be obtained by applying the exponential function to the coefficient. For further details, see the *Odds Ratios* section in the *Technical Methods* chapter of the *Executive Summary*.

**Table V-11. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Short Term Pancreas Transplant Survival**

| Short Term Characteristics | Graft Survival | | | | Patient Survival | | | |
|---|---|---|---|---|---|---|---|---|
| | 3 Months | | 1 Year | | 3 Months | | 1 Year | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| Intercept | -1.265 | 0.162 | -1.038 | 0.151 | -2.699 | 0.296 | -1.992 | 0.219 |
| Donor Age - Linear (per 10 years)[1,2] | 0.214 | 0.038 | 0.196 | 0.034 | 0.221 | 0.098 | 0.110 | 0.064 |
| -Quadratic (per 10 years) | --- | --- | --- | --- | -0.106 | 0.066 | -0.028 | 0.041 |
| Cold Ischemic Time (per hour)[1] | --- | --- | --- | --- | -0.031 | 0.017 | -0.015 | 0.011 |
| Previous Pancreas Transplant -- Yes vs No | 0.112 | 0.243 | 0.616 | 0.215 | --- | --- | --- | --- |
| Recipient Age -Linear (per 10 years)[1,2] | 0.003 | 0.070 | 0.036 | 0.060 | 0.026 | 0.133 | 0.308 | 0.090 |
| -Quadratic (per 10 years) | 0.019 | 0.072 | 0.102 | 0.061 | --- | --- | --- | --- |
| Recipient Black vs non-Black | --- | --- | --- | --- | 0.529 | 0.361 | -0.070 | 0.310 |
| Pancreas After Kidney vs Simultaneous Kidney-Pancreas | 0.749 | 0.191 | 0.884 | 0.172 | --- | --- | --- | --- |
| Pancreas Alone vs Simultaneous Kidney-Pancreas | 0.380 | 0.181 | 1.067 | 0.150 | --- | --- | --- | --- |
| TX Year 1989 vs 1988 | -0.462 | 0.206 | -0.187 | 0.186 | -0.184 | 0.365 | -0.226 | 0.274 |
| TX Year 1990 vs 1988 | -0.279 | 0.192 | 0.139 | 0.175 | -0.061 | 0.342 | -0.032 | 0.254 |
| TX Year 1991 vs 1988 | -0.668 | 0.201 | -0.388 | 0.180 | -0.349 | 0.361 | -0.548 | 0.274 |
| TX Year 1992 vs 1988 | -0.595 | 0.198 | -0.426 | 0.180 | -0.391 | 0.362 | -0.315 | 0.262 |
| TX Year 1993-1994 vs 1988 | -0.608 | 0.180 | -0.321 | 0.164 | -1.059 | 0.361 | -0.529 | 0.247 |

Notes:

1 In the analysis, the continuous covariates (donor age, cold ischemic time, and recipient age) were centered at their mean. The mean donor age was 28. The mean cold ischemic time was 14 hours. The mean recipient age was 36.

2 Modeling the continuous covariates with a linear and a quadratic term (the square of the linear term) is necessary due to the relationship between the covariate and the odds of graft failure or patient death.

**Table V-12. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Long Term Pancreas Transplant Survival**

| Long Term Characteristics | Graft Survival | | Patient Survival | |
|---|---|---|---|---|
| | Model Coefficient | Standard Error | Model Coefficient | Standard Error |
| **Intercept** | -2.704 | 0.122 | -2.848 | 0.153 |
| **Donor Age - Linear (per 10 years)[1]** | --- | --- | 0.209 | 0.079 |
| **Donor Black vs Non-Black** | --- | --- | 0.573 | 0.318 |
| **Cold Ischemic Time - Linear (per hour)[1,2]** | --- | --- | -0.016 | 0.015 |
| **-Quadratic (per hour)** | --- | --- | 0.004 | 0.002 |
| **Recipient Age - Linear (per 10 years)[1,2]** | --- | --- | 0.112 | 0.158 |
| **-Quadratic (per 10 years)** | --- | --- | 0.207 | 0.140 |
| **Years Between Diabetes Onset and Transplant - Linear (per year)[1]** | --- | --- | 0.026 | 0.017 |
| **Pancreas After Kidney vs Simultaneous Kidney-Pancreas** | 1.826 | 0.313 | --- | --- |
| **Pancreas Alone vs Simultaneous Kidney-Pancreas** | 1.988 | 0.287 | --- | --- |

Notes:

[1] In the analysis, the continuous covariates (donor age, cold ischemic time, and recipient age) were centered at their mean. The mean donor age was 28. The mean cold ischemic time was 14 hours. The mean recipient age was 36. The mean years between diabetes onset and transplant was 23 years.

[2] Modeling the continuous covariates with a linear and a quadratic term (the square of the linear term) is necessary due to the curvilinear relationship between the covariate and the odds of graft failure or patient death.

## Expected Pancreas Transplant Survival Rates

Table V-13 shows the 1 year *expected graft* survival rates for pancreas transplants for a given set of donor and recipient characteristics; Table V-14 shows the 1 year *expected patient* survival rates. These rates were determined using the following characteristics: recipient age, donor age, and procedure type. For these analyses, all other characteristics were set to the values for the reference groups, with the exception of the year of transplant (1993 or 1994). The complete list of reference groups is shown on page 77.

For example, in Table V-13, the expected 1 year graft survival for a 35 year old recipient of a pancreas alone from a 20 year old donor was 61%. In contrast, a simultaneous kidney-pancreas transplant of a 20 year old donor into a 35 year old recipient was 82%. Please note that procedure type did not significantly impact 1 year patient survival, so there was no difference reported in expected 1 year patient survival across procedure types.

Table V-13. Expected U.S. 1 Year Graft Survival Rates--Pancreas Transplants Stratified by Recipient Age, Donor Age, and Procedure Type

| Recipient Age | Donor Age | Procedure Type | | |
|---|---|---|---|---|
| | | Simultaneous Kidney-Pancreas | Pancreas After Kidney | Pancreas Alone |
| 20 | 20 | 78.73 | 60.47 | 56.02 |
| | 30 | 75.27 | 55.71 | 51.16 |
| | 35 | 73.41 | 53.28 | 48.71 |
| | 40 | 71.45 | 50.84 | 46.27 |
| | 50 | 67.30 | 45.95 | 41.46 |
| 30 | 20 | 81.65 | 64.77 | 60.49 |
| | 30 | 78.54 | 60.19 | 55.73 |
| | 35 | 76.84 | 57.82 | 53.31 |
| | 40 | 75.05 | 55.42 | 50.87 |
| | 50 | 71.21 | 50.54 | 45.98 |
| 35 | 20 | 81.89 | 65.13 | 60.87 |
| | 30 | 78.80 | 60.56 | 56.12 |
| | 35 | 77.12 | 58.20 | 53.70 |
| | 40 | 75.35 | 55.80 | 51.26 |
| | 50 | 71.54 | 50.94 | 46.37 |
| 40 | 20 | 81.36 | 64.32 | 60.03 |
| | 30 | 78.21 | 59.72 | 55.25 |
| | 35 | 76.49 | 57.34 | 52.82 |
| | 40 | 74.69 | 54.93 | 50.38 |
| | 50 | 70.81 | 50.06 | 45.50 |
| 50 | 20 | 77.74 | 59.06 | 54.58 |
| | 30 | 74.17 | 54.26 | 49.70 |
| | 35 | 72.25 | 51.82 | 47.26 |
| | 40 | 70.25 | 49.38 | 44.83 |
| | 50 | 66.00 | 44.51 | 40.05 |

**Table V-14. Expected U.S. 1 Year Patient Survival Rates--Pancreas Transplants Stratified by Recipient Age, Donor Age, and Procedure Type**

| Recipient Age | Donor Age | Procedure Type | | |
|---|---|---|---|---|
| | | Simultaneous Kidney-Pancreas | Pancreas After Kidney | Pancreas Alone |
| 20 | 20 | 95.71 | 95.71 | 95.71 |
| | 30 | 95.17 | 95.17 | 95.17 |
| | 35 | 94.98 | 94.98 | 94.98 |
| | 40 | 94.85 | 94.85 | 94.85 |
| | 50 | 94.80 | 94.80 | 94.80 |
| 30 | 20 | 94.25 | 94.25 | 94.25 |
| | 30 | 93.55 | 93.55 | 93.55 |
| | 35 | 93.30 | 93.30 | 93.30 |
| | 40 | 93.13 | 93.13 | 93.13 |
| | 50 | 93.06 | 93.06 | 93.06 |
| 35 | 20 | 93.36 | 93.36 | 93.36 |
| | 30 | 92.55 | 92.55 | 92.55 |
| | 35 | 92.27 | 92.27 | 92.27 |
| | 40 | 92.08 | 92.08 | 92.08 |
| | 50 | 92.00 | 92.00 | 92.00 |
| 40 | 20 | 92.34 | 92.34 | 92.34 |
| | 30 | 91.42 | 91.42 | 91.42 |
| | 35 | 91.10 | 91.10 | 91.10 |
| | 40 | 90.88 | 90.88 | 90.88 |
| | 50 | 90.79 | 90.79 | 90.79 |
| 50 | 20 | 89.86 | 89.86 | 89.86 |
| | 30 | 88.68 | 88.68 | 88.68 |
| | 35 | 88.27 | 88.27 | 88.27 |
| | 40 | 87.99 | 87.99 | 87.99 |
| | 50 | 87.88 | 87.88 | 87.88 |

## J. SUMMARY

### Study Period

The 1997 Report was based on 3,222 pancreas transplants performed in 3,142 patients between January 1, 1988, and April 30, 1994, from 96 transplant programs in the United States. In order to assess changes within transplant programs over time, the data were divided into 2 eras. The first era included transplants performed from January 1, 1988, through April 30, 1992; and the second era covered the two year time period from May 1, 1992, through April 30, 1994.

### Survival Rates

Survival rates were computed at 3 months, 1 year, and 3 years, both nationally and for each transplant program. Three year survival was determined in two ways: (1) conditional 3 year survival (i.e., survival at 3 years for those who survived at least 1 year post-transplant), and (2) unconditional 3 year survival. The emphasis on long term survival in this chapter is on the conditional 3-year survival rates because the conditional 3-year analysis provides an assessment of characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

The national graft and patient survival rates and completeness of follow-up at 3 months, 1 year, and conditional 3 years are shown in Tables V-1 and V-2. The percent of programs with graft and patient follow-up data at 1 year was more than 96%; at conditional 3 years the percent of programs with follow-up data was 94%.

There was a marked increase in both the number of pancreas transplants and in the actual graft and patient survival rates from Era 1 to Era 2. As demonstrated in Table V-15, graft survival rates increased 2.8% at 3 months and 3.8% at 1 year in Era 2 from Era 1. Patient survival rates increased 2.6% at 3 months and 1.7% at 1 year during the study period.

For the majority of transplant programs, the difference between actual and expected survival rates was not statistically significant (See Figures V-1 and V-3). In general, large differences (either higher or lower) were nearly always found among programs that reported relatively few transplants (see Figure V-2). Therefore, when evaluating survival rates for a program, it is also important to consider the number of transplants performed there.

**Table V-15. Comparison of 3 Month and 1 Year Actual Survival Rates Between Eras**

| | 3 Months | | 1 Year | |
|---|---|---|---|---|
| | Era 1 | Era 2 | Era 1 | Era 2 |
| Graft Survival (%) | 82.4% | 85.2% | 71.9% | 75.7% |
| Average No. of Transplants/ Month | 35.1 | 58.2 | 35.1 | 58.2 |
| Patient Survival (%) | 94.9% | 97.5% | 90.4% | 92.1% |
| Average No. of Patients/Month | 34.5 | 57.5 | 34.5 | 57.5 |

**Differences Between Short Term and Long Term Characteristics**

The 1997 Report includes an extensive list of characteristics that have a significant impact on both short and long term graft and patient survival.

Characteristics with the strongest impact on *short term graft survival* were:

- Procedure type
- Previous pancreas transplant
- Year of transplant

Characteristics with the strongest impact on *short term patient survival* were:

- Recipient race
- Recipient age
- Donor age
- Year of transplant

Characteristic with the strongest impact on *long term graft survival* was:

- Procedure type

Characteristics with the strongest impact on *long term patient survival* were:

- Donor race
- Donor age
- Recipient age

## K. FINAL WORDS

The purpose of this report is to provide updated information on survival outcomes both nationally and at specific transplant programs, and to enhance the awareness of program performance in the U.S. However, the assessment of a transplant program should not be based solely on the survival rates provided in this report. Some of the other important factors to consider are the experience of the transplant team, support personnel, the cost of the procedure, and the quality and location of post-transplant services.

# VI. HEART CHAPTER

Introduction
Completeness of Follow-Up Data and Survival Rates
Percentages of Actual and Expected Graft Survival Rates
Percentages of Actual and Expected Patient Survival Rates
Donor and Recipient Characteristics
Impact of Characteristics on Short Term Survival
Impact of Characteristics on Long Term Survival
Comparison Between Short and Long Term Characteristics
Statistical Methods and Models
Summary
Final Words

# VI. HEART TRANSPLANT SURVIVAL RATES

*For the Summary of this chapter, see page 101. For definitions of any terms used here, please refer to the User's Guide in the Heart volume.*

## A. INTRODUCTION

This report of heart transplant survival rates is based upon verified Scientific Registry data for 12,627 transplants involving 12,428 patients from 161 heart transplant programs in the United States. Each program reporting at least one heart transplant between January 1, 1988, and April 30, 1994, was included. Multi-organ, heterotopic and living donor transplants were excluded.

Short term survival is defined as survival at 1 month and 1 year post-transplant. Short term survival rates are based on all transplants in the study for which there are follow-up data.

Long term survival is defined in two ways:

- unconditional survival at 3 years post-transplant, and
- survival at 3 years post-transplant for those who survived at least 1 year, referred to as **conditional 3 year survival.**

The long term survival rates are based on all transplants between January 1, 1988, and April 30, 1992, for which there are follow-up data. This cohort was chosen to ensure that the maximum number of transplants with follow-up data was used to determine long term survival rates. Please note that this report emphasizes *conditional* 3-year survival rates. This is because the conditional 3-year analysis assesses characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

## B. COMPLETENESS OF FOLLOW-UP DATA AND OVERALL GRAFT AND PATIENT SURVIVAL RATES

For graft survival, completeness of follow-up data and overall actual survival rates at each time point are shown in Table VI-1; patient survival data are shown in Table VI-2.

Patient (graft) follow-up data were considered complete when:

- the patient was alive (heart was functioning) and the duration of survival (function) was equal to or exceeded the specified time after transplant (i.e., 1 month, 1 or 3 years), or
- the patient died (heart failed) and a valid date of death (failure) was reported.

The percentages of complete follow-up data ranged from a low of 97.9% for the conditional 3 year time point to a high of 99.7% for the 1 month time point. Patient survival rates are similar to graft survival rates since patient death follows graft failure unless the patient is retransplanted.

Overall survival rates also are presented in the tables. If a graft had incomplete follow-up data, the observation was weighted to account for the time during which the graft was known to be functioning. Therefore, the actual graft survival rate reflects the weighted proportion of grafts functioning at the specified time interval. Patient survival rates were computed in a similar way (see the *Technical Methods* chapter of the *Executive Summary*).

In the cohort of transplants (1/1/88 - 4/30/92) used to compute conditional 3 year survival rates, patients (grafts) who did not survive to 1 year after transplant were excluded from the analyses. Therefore, the total number of patients (grafts) for the conditional 3 year analysis was less than that for the 1 month and 1 year analyses.

Please note that the conditional 3 year graft and patient survival rates in Tables VI-1 and VI-2 may be higher than the 1 year graft survival rates. This is possible because the conditional 3 year survival rate is the 3 year survival rate for patients (grafts) who (which) survived at least 1 year post-transplant.

For example: Program A performed a total of five transplants between 1/1/88 and 4/30/92. Two of the hearts failed prior to 1 year post-transplant and the remaining three hearts survived to 3 years after

transplant. In this example, Program A has a 1 year graft survival rate of 60% (3 out of 5 hearts were functioning at 1 year post-transplant). However, the conditional 3 year survival rate for Program A is 100% because all three hearts that were functioning at 1 year after transplant also were functioning at 3 years post-transplant. The same calculations are used for patient survival. See the *Technical Methods* chapter of the *Executive Summary* for more specific definitions of follow-up data and the calculations for actual graft and patient survival.

Overall Graft and Patient Survival Rates by Era

In this report, short term survival also is reported by era. Separate eras were used to determine whether there were any improvements over time in the short term survival rates. Era 1 is defined as all transplants occurring between January 1, 1988, and April 30, 1992; Era 2 includes all transplants occurring between May 1, 1992, and April 30, 1994. The overall graft and patient survival rates by era are presented in the last two columns of Table VI-1 and Table VI-2, respectively. The results demonstrate consistent high graft and patient survival rates over time.

## C. GRAFT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

For each transplant program, actual and expected survival rates were calculated at 1 month, 1 year, and 3 years conditional on survival at 1 year. Survival rates at each time point were determined using a specific cohort of transplants (shown in Tables VI-1 and VI-2). Expected survival rates were determined for each transplant program based on its specific patient and donor characteristics. These expected outcomes were statistically adjusted for many important prognostic variables, or covariates, that were used in the survival analysis. In other words, they take into account the many different characteristics that affect survival. For example: *if Program A transplanted many more "high risk" recipients than Program B, then Program A would*

**Table VI-1. Completeness of Graft Follow-Up Data and Actual Survival Rates for Heart Transplants**

| Time | Cohort | Number of Transplants | Percent with Follow-Up Data | Graft Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 1 Month | 1/1/88 - 4/30/94 | 12,627 | 99.7 | 91.6 | 91.6 | 91.5 |
| 1 Year | 1/1/88 - 4/30/94 | 12,627 | 98.9 | 81.7 | 81.5 | 81.9 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 6640 | 98.0 | 90.2* | 90.2* | N/A* |

**Table VI-2. Completeness of Patient Follow-Up Data and Actual Survival Rates for Heart Transplants**

| Time | Cohort | Number of Patients | Percent with Follow-Up Data | Patient Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 1 Month | 1/1/88 - 4/30/94 | 12428 | 99.7 | 92.1 | 92.1 | 92.0 |
| 1 Year | 1/1/88 - 4/30/94 | 12428 | 98.9 | 82.5 | 82.4 | 82.8 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 6620 | 97.9 | 90.7* | 90.7* | N/A* |

* The cohort used to determine the overall conditional 3 year survival rate is the same as the Era 1 cohort. Therefore, the overall conditional 3 year survival rates are identical to the conditional 3 year survival rates for Era 1. There is no conditional 3 year survival rate calculated for Era 2 due to insufficient follow-up data on patients who received transplants in Era 2.

*have a lower expected survival rate than Program B.*

If a program's *actual* survival rate was *greater* than its expected survival rate, this means that the program's actual results were higher than the national results for transplants *with the same donor and recipient characteristics*. If a program's *actual* survival rate was *less than* its expected survival rate, this means that the program's actual results were lower than the national results for transplants *with the same donor and recipient characteristics. The difference between actual and expected rate may have occurred by chance, and therefore, may not be statistically significant.* Furthermore, even a statistically significant difference, one that most likely did not occur by chance, may not be clinically significant (i.e. medically important). A formal description of the methods used to determine actual and expected rates appears in the *Technical Methods* chapter of the *Executive Summary*.

Table VI-3 shows the percentages of heart transplant programs by category of graft survival rates, both for actual and expected survival. The majority of the transplant programs had actual survival rates greater than 70% at all time points. The 1 year survival rates showed a greater variation among programs than the 1 month and conditional 3 year survival rates. At 1 month, 61% of programs had actual survival rates greater than 90%. At 1 year, this fell to 13%. However, this percentage increased to 57% for the conditional 3 year survival rates. The distribution of the expected survival rates shows a similar trend. The results indicate that there are more programs with high survival rates (>90%) at the conditional 3 year time point than there are at the 1 year time point. *This is because the most critical period of time for graft survival is the first year post-transplant.* Those who survive the first year are very likely to survive 3 years post-transplant.

The percentages of programs by short term graft survival rates and eras, both for actual and expected survival, are summarized in Table VI-4. The results demonstrate a slight improvement in graft survival over time because a greater percentage of programs had actual survival rates higher than 90% in Era 2.

**Differences in Actual and Expected Survival Rates**

For most programs, the difference between the actual survival rate and the expected survival rate was not statistically significant. Figure VI-1 shows the percentages of programs whose actual graft survival rates were either above, not significantly different, or below expected graft survival rates at three time points. Actual survival rates shown in the figure to be either greater than or less than expected survival rates were statistically significant. Overall, there were more programs that fell significantly below expected results than programs that where significantly above expected results. However, for

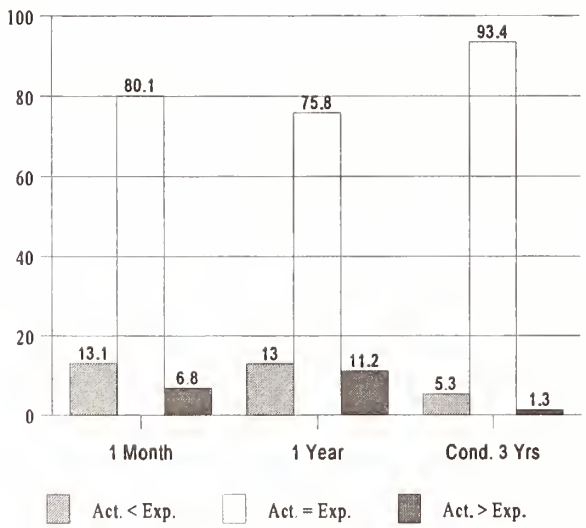
**Table VI-3. Percentages of Heart Transplant Programs by Graft Survival Rates**

| Graft Survival Rates (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 1 Month (n= 161) | 1 Year (n=161) | Cond. 3 Yrs (n=150) | 1 Month (n=161) | 1 Year (n=161) | Cond. 3 Yrs (n=150) |
| 0-60 | 3.7 | 10.6 | 2.7 | 0.0 | 0.0 | 0.0 |
| >60-70 | 1.8 | 8.1 | 2.6 | 0.0 | 6.2 | 0.7 |
| >70-80 | 5.6 | 32.3 | 7.3 | 0.6 | 16.1 | 0.0 |
| >80-90 | 28.0 | 36.0 | 30.7 | 16.8 | 77.6 | 40.0 |
| >90-100 | 60.9 | 13.0 | 56.7 | 82.6 | 0.0 | 59.3 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Table VI-4. Percentages of Heart Transplant Programs by Graft Survival Rates and Era**

| Graft Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Era 1 (n=153) | Era 2 (n=150) | Era 1 (n=153) | Era 2 (n=150) | Era 1 (n=153) | Era 2 (n=150) | Era 1 (n=153) | Era 2 (n=150) |
| 0-60 | 5.2 | 2.7 | 11.8 | 8.7 | 0.0 | 0.0 | 0.0 | 0.0 |
| >60-70 | 1.3 | 3.3 | 9.8 | 10.0 | 0.0 | 0.0 | 7.2 | 4.0 |
| >70-80 | 7.2 | 5.3 | 26.8 | 20.6 | 2.6 | 0.0 | 13.7 | 21.3 |
| >80-90 | 26.1 | 24.7 | 34.6 | 36.0 | 17.0 | 18.7 | 79.1 | 74.7 |
| >90-100 | 60.1 | 64.0 | 17.0 | 24.7 | 80.4 | 81.3 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Figure VI-1. Percentages of Heart Transplant Programs with Actual Graft Survival Rates Above, Below, or Equal to Expected Survival Rates. ***

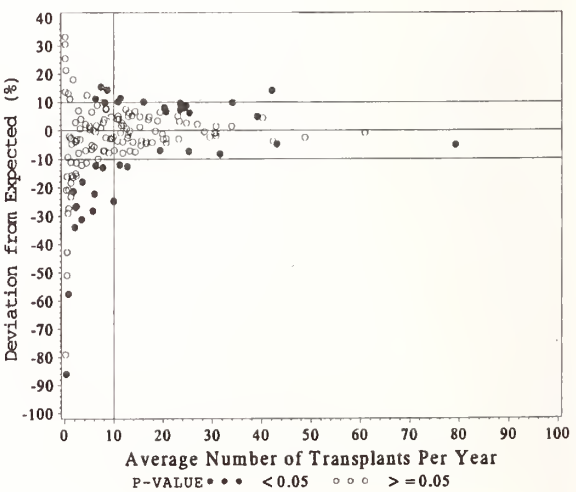



*Actual survival rates above or below expected survival rates are statistically significant and varied little across time points.

the majority of the transplant programs, the difference in actual and expected graft survival was not statistically significant and varied little across time points.

At all time points, the larger differences in actual and expected rates were nearly always seen in programs that reported relatively few transplants during the period. This occurs because programs that do not perform many transplants tend to have highly variable outcomes. To illustrate this, Figure VI-2 shows a scatter plot of the average number of transplants per year (transplant volume) versus the difference in 1 year actual and expected graft survival. Nearly all differences greater than 10% (either positive or negative) are found among

**Figure VI-2. Heart Transplant Volume vs Difference in Actual and Expected 1 Year Graft Survival Rates.**



transplant programs performing fewer than 10 heart transplants per year.

*Please note that actual survival rates which differ from expected survival rates are not always statistically significant and even statistically significant differences may not be clinically significant.*

## D. PATIENT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

The percentages of programs by patient survival rates for both actual and expected survival are shown in Table VI-5; the percentages of programs by survival rates and eras are shown in Table VI-6. Note that both actual and expected patient survival rates were higher and less variable at each time point than were actual and expected graft survival rates. As with graft survival, the outcomes in Era 2 were better than in Era 1.

### Differences in Actual and Expected Survival Rates

The percentage of programs with actual patient survival rates significantly above their expected rates was greatest at 1 year (see Figure VI-3). Overall, there were more programs that fell significantly

**Table VI-5. Percentages of Heart Transplant Programs by Patient Survival Rates**

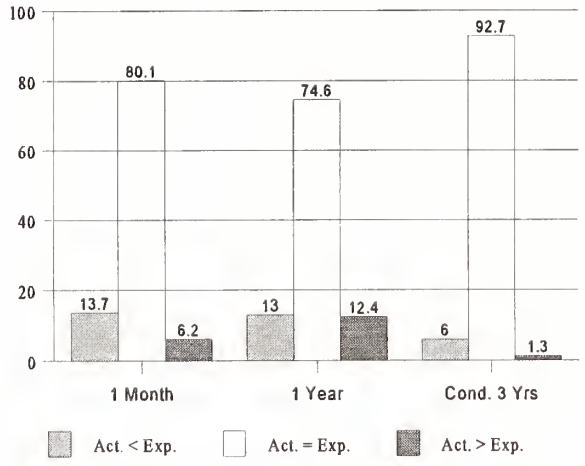
| Patient Survival Rates (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 1 Month (n= 161) | 1 Year (n=161) | Cond. 3 Yrs (n=150) | 1 Month (n=161) | 1 Year (n=161) | Cond. 3 Yrs (n=150) |
| 0-70 | 5.6 | 18.0 | 5.3 | 0.0 | 3.7 | 0.0 |
| >70-80 | 5.6 | 26.7 | 7.3 | 0.0 | 14.3 | 0.7 |
| >80-90 | 25.5 | 41.0 | 28.0 | 16.8 | 82.0 | 29.3 |
| >90-95 | 32.9 | 7.5 | 34.7 | 81.4 | 0.0 | 70.0 |
| >95-100 | 30.4 | 6.8 | 24.7 | 1.9 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Table VI-6. Percentages of Heart Transplant Programs by Patient Survival Rates and Era**

| Patient Survival Rate (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Era 1 (n=153) | Era 2 (n=150) | Era 1 (n=153) | Era 2 (n=150) | Era 1 (n=153) | Era 2 (n=150) | Era 1 (n=153) | Era 2 (n=150) |
| 0-70 | 6.5 | 5.3 | 19.0 | 16.7 | 0.0 | 0.0 | 5.2 | 2.0 |
| >70-80 | 6.5 | 5.3 | 24.8 | 19.3 | 1.3 | 0.0 | 13.1 | 18.0 |
| >80-90 | 24.2 | 22.7 | 37.3 | 38.0 | 15.0 | 18.0 | 81.7 | 80.0 |
| >90-95 | 26.8 | 24.7 | 11.1 | 14.0 | 81.0 | 79.3 | 0.0 | 0.0 |
| >95-100 | 35.9 | 42.0 | 7.8 | 12.0 | 2.6 | 2.7 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

below expected results than above expected results. However, for the majority of transplant programs, the difference in actual and expected patient survival was not statistically significant and varied little across time points.

**Figure VI-3. Percentages of Heart Transplant Programs with Actual Patient Survival Rates Above, Below or Equal to Expected Survival Rates. ***




*Actual survival rates above or below expected survival rates are statistically significant and varied little across time points.

## E. NATIONAL DISTRIBUTION OF DONOR AND RECIPIENT CHARACTERISTICS

The national distribution of donor and recipient characteristics for heart transplants, presented in percentages, is shown in Table VI-7. Each of these donor and recipient characteristics was included in the analyses for graft or patient survival, and used to determine an expected survival rate for each transplant. The majority of hearts transplanted were recovered from white male donors between the ages of 18 and 49. Forty-five percent of the donor hearts had cold ischemic times less than 2.5 hours. The majority of heart recipients were white males greater than 50 years of age. Most recipients were either not hospitalized (46%) or in the ICU (45%) prior to transplant. The main indication for transplant was evenly divided between coronary artery disease (41%) and cardiomyopathy (46%). Of the 12,627 heart transplants performed, less than 3% were due to repeat transplants.

### Donor and Recipient Trends

National donor and recipient characteristics differed slightly between Era 1 and Era 2. There was an increase in the percentage of younger donors in Era 2, and the percent of donors older than 50 years almost doubled (3.6% to 6.5%). There was a 5% increase in the percentage of minority donors from Era 1 to Era 2. Transplant recipients were older in the second era; those over age 49 comprised 56% of recipients in Era 2 as compared to 53% in Era 1. More minorities were transplanted in Era 2 than in Era 1. Cardiomyopathy accounted for just under half of all diagnosis in Era 2 compared to only 44% in Era 1. More recipients were in the ICU at time of transplant in Era 2 than in Era 1. Also, mean cold ischemic time increased 4% from Era 1 to Era 2.

## F. SHORT TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

To determine the expected survival for each transplant or patient, separate analyses were performed for graft and patient survival at three time points. (The analyses were performed using logistic regression, for a description see the *Technical Methods* chapter in the *Executive Summary.*) The analyses also identified donor and recipient characteristics that had a significant impact on survival outcomes. For each *characteristic* (e.g., race, gender) considered in the analyses, a *reference group* was chosen (e.g., White, male) with which the other groups were compared. As a general rule, the largest group or the mean of the characteristic (e.g., mean recipient age=45) is often used as the reference group.

The following served as the characteristics and reference groups for ***short term graft and patient*** survival:

- Mean Donor Age -- 26 years
- Donor Race -- White
- Donor Gender -- male
- Mean Cold Ischemic Time -- 163 minutes
- Previous Heart Transplant -- none
- Mean Recipient Age -- 45 years
- Recipient Race -- non-Black
- Recipient Gender -- male

(Cont.)

**Table VI-7. National Donor and Recipient Characteristics in Heart Transplants: Percentages by Era and Overall.**

| Risk Factor by Category | | ERA 1 1/88-4/92 N=8192 | ERA 2 5/92-4/94 N=4435 | OVERALL 1/88-4/94 N=12627 |
|---|---|---|---|---|
| **Donor Age (years)** | 0-5 | 6.2 | 6.7 | 6.3 |
| | 6-10 | 1.9 | 2.6 | 2.2 |
| | 11-17 | 15.1 | 17.9 | 16.1 |
| | 18-49 | 73.2 | 66.0 | 70.7 |
| | 50-64 | 3.6 | 6.5 | 4.7 |
| | 65+ | 0.0 | 0.2 | 0.1 |
| **Donor Gender** | Female | 29.0 | 30.5 | 29.5 |
| | Male | 71.0 | 69.5 | 70.5 |
| **Donor Race** | White | 81.1 | 76.5 | 79.5 |
| | Black | 9.1 | 11.7 | 10.0 |
| | Hispanic | 8.4 | 10.2 | 9.1 |
| | Asian | 0.7 | 0.8 | 0.7 |
| | Other | 0.7 | 0.7 | 0.7 |
| | Not Reported | 0.0 | 0.1 | 0.1 |
| **Recipient Age (years)** | <1 | 4.4 | 4.3 | 4.3 |
| | 1-10 | 3.1 | 4.1 | 3.4 |
| | 11-17 | 2.8 | 2.9 | 2.8 |
| | 18-49 | 37.2 | 32.6 | 35.6 |
| | 50-64 | 49.8 | 51.8 | 50.5 |
| | 65+ | 2.8 | 4.3 | 3.3 |
| **Recipient Gender** | Female | 21.5 | 22.6 | 21.9 |
| | Male | 78.5 | 77.4 | 78.1 |
| **Recipient Race** | White | 84.3 | 81.1 | 83.2 |
| | Black | 8.9 | 10.7 | 9.6 |
| | Hispanic | 4.3 | 5.0 | 4.5 |
| | Asian | 0.7 | 1.4 | 1.0 |
| | Other | 1.7 | 1.7 | 1.7 |
| | Not Reported | 0.0 | 0.0 | 0.0 |
| **Previous Heart Transplant** | No | 97.2 | 96.2 | 96.9 |
| | Yes | 2.8 | 2.7 | 2.7 |
| | Not Reported | 0.0 | 1.1 | 0.4 |

| | | ERA 1 | ERA 2 | OVERALL |
|---|---|---|---|---|
| **On Ventilator at Transplant** | No | 94.3 | 93.9 | 94.2 |
| | Yes | 5.3 | 5.2 | 5.3 |
| | Not Reported | 0.4 | 0.9 | 0.6 |
| **On VAD at Transplant** | No | 97.3 | 95.0 | 96.5 |
| | Yes | 2.2 | 4.1 | 2.9 |
| | Not Reported | 0.4 | 0.9 | 0.6 |
| **On IABP at Transplant** | No | 92.8 | 93.5 | 93.1 |
| | Yes | 6.8 | 5.6 | 6.3 |
| | Not Reported | 0.4 | 0.9 | 0.6 |
| **Diagnosis at Transplant** | Coronary Artery Disease | 43.3 | 37.7 | 41.4 |
| | Cardiomyopathy | 43.8 | 49.4 | 45.8 |
| | Eisenmenger's Syndrome/Congenital | 7.1 | 8.0 | 7.4 |
| | Valvular Heart Disease | 4.2 | 3.0 | 3.8 |
| | Other Diagnosis | 1.3 | 1.6 | 1.4 |
| | Not Reported | 0.3 | 0.2 | 0.3 |
| **Medical Condition at Transplant** | In ICU | 45.2 | 52.2 | 47.7 |
| | Hospitalized | 8.8 | 6.0 | 7.8 |
| | Not Hospitalized | 45.9 | 41.6 | 44.4 |
| | Not Reported | 0.1 | 0.2 | 0.1 |
| **Cold Ischemic Time** | Up to 2 hrs | 29.6 | 23.2 | 27.4 |
| | > 2 - 2.5 hrs | 18.3 | 17.4 | 18.0 |
| | > 2.5 - 3 hrs | 18.2 | 20.7 | 19.1 |
| | > 3 - 3.5 hrs | 14.8 | 16.5 | 15.4 |
| | > 3.5 hrs | 18.1 | 21.9 | 19.4 |
| | Not Reported | 0.9 | 0.2 | 0.7 |
| **Year of Transplant** | 1988 | 20.1 | 0.0 | 13.1 |
| | 1989 | 20.5 | 0.0 | 13.3 |
| | 1990 | 25.3 | 0.0 | 16.4 |
| | 1991 | 25.6 | 0.0 | 16.6 |
| | 1992 | 8.5 | 32.6 | 17.0 |
| | 1993 | 0.0 | 51.1 | 17.9 |
| | 1994 | 0.0 | 16.3 | 5.7 |

- Primary Heart Disease -- cardiomyopathy (see Table VI-8 for a complete list of disease diagnoses)
- Medical Status -- not in ICU prior to transplant
- On Ventilator at Transplant -- no
- On VAD at Transplant -- no
- On IABP at Transplant -- no
- Year of Transplant -- 1988-1992

The relative impact of each donor and recipient characteristic on short term graft and patient survival outcomes is listed in Table VI-9. For each characteristic, the ***odds ratio*** is the odds of patient death (graft failure) as compared to the reference group, after adjusting for the effects of all other donor and recipient characteristics. An *odds ratio of less than 1* indicates that the characteristic was associated with a *reduced odds* of patient death or graft failure relative to the reference group. An odds ratio of *greater than 1* indicates that the characteristic was associated with an *increased odds* of death relative to the reference group. The corresponding p-value measures how significant the odds ratio is. A p-value less than 0.05 indicates statistical significance and means that there is less than a 5% probability that such difference is due to chance alone. The smaller the p-value, the greater the statistical significance and the less likely the difference is due to chance alone.

**Examples**

In Table VI-9, the odds ratio of graft failure within 1 month, if the recipient was in the ICU at time of transplant, was 1.31. This means that, after adjusting for all of the other donor and recipient characteristics, the odds of graft failure within 1 month was 31% greater for recipients in the ICU than for those hospitalized or at home at time of transplant ((1.31-1)×100%=31%). As another example, the odds ratio of graft failure within 1 month post-transplant for a recipient who had a previous transplant versus a recipient who received a first transplant was 2.39. After adjusting for the effects of both donor and recipient characteristics, the odds of graft failure within 1 month for a patient who had a previous transplant was 139% higher ((2.39-1)×100%=139%) than that for a patient who received a first transplant.

The estimated odds ratios for continuous variables (i.e., variables with many possible values) such as cold ischemic time and donor and recipient ages, are less easily interpreted. For these variables, the estimated odds is determined for every 10 or 15 unit increase or decrease from the mean (reference group) of the variable. For example, in Table VI-9, the estimated odds of 1 month graft failure for 178 minutes of cold ischemic time compared to the mean of 163 minutes is 1.03. This means that, after adjusting for the effects of all other characteristics, the odds of graft failure was estimated to increase by 3% for the first 15 minute increase from the mean cold ischemic time.

An increase of 1 hour (60 minutes) from the mean cold time (i.e., the cold ischemic time is 163 min+60 min=223 min) would result in an 12% increase in the odds of graft failure at 1 month.

Mathematically, this 12% was calculated as follows:

$$\text{Odds ratio} = \exp^{\left(\frac{60}{15} \times 0.0296\right)} = 1.12$$

**Table VII-8. Heart Primary Disease Diagnoses at Time of Transplant**

| |
|---|
| Coronary Artery Disease |
| Valvular Heart Disease |
| Congenital Heart Disease |
| Cardiomyopathy |
| -Dilated |
| - Idiopathic, Adriamycin, Post Partum, Familial, Myocarditis, Alcoholic, Viral, Ischemic, Other |
| -Restrictive |
| - Idiopathic, Amyloidosis, Endocardial Fibrosis, Sarcoidosis |
| -Hypertrophic |
| Other |
| -Retransplant due to: |
| - Hyperacute Rejection, Acute Rejection, Coronary Artery Disease, non-Specific, Restrictive/Constrictive |
| -Eisenmenger's syndrome: Ventricular Septal Defect |
| -Primary Pulmonary Hypertension |
| -Cystic Fibrosis |
| -Other |

**Table VI-9. Impact of Donor and Recipient Characteristics on Short Term Graft and Patient Survival--Heart Transplants**

| Short Term Risk Characteristics | Graft Survival | | | | Patient Survival | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Odds Ratio | P-value | Odds Ratio | P-value | Odds Ratio | P-value | Odds Ratio | P-value |
| Donor Age 36 vs 26 [1] | 1.169 | <0.001 | 1.140 | <0.001 | 1.167 | <0.001 | 1.142 | <0.001 |
| Donor Black vs White | 0.882 | 0.276 | 1.149 | 0.074 | 0.885 | 0.306 | 1.154 | 0.073 |
| Donor Hispanic vs White | 1.141 | 0.234 | 1.276 | 0.002 | 1.169 | 0.170 | 1.272 | 0.003 |
| Donor Asian, Other vs White | 0.837 | 0.529 | 1.463 | 0.034 | 0.855 | 0.593 | 1.483 | 0.032 |
| Donor Female vs Male | 1.264 | 0.001 | 1.171 | 0.003 | 1.232 | 0.005 | 1.154 | 0.008 |
| Cold Ischemic Time - 178 min vs 163 min [1] | 1.030 | <0.001 | 1.022 | <0.001 | 1.029 | <0.001 | 1.021 | <0.001 |
| Recipient Age 55 vs 45 [1] | 1.118 | <0.001 | 1.151 | <0.001 | 1.138 | <0.001 | 1.171 | <0.001 |
| Recipient Age <=1 | 0.670 | 0.065 | 0.945 | 0.743 | 0.700 | 0.111 | 0.958 | 0.811 |
| Recipient Female vs Male | 1.283 | 0.002 | 1.099 | 0.108 | 1.289 | 0.002 | 1.095 | 0.135 |
| Recipient in ICU vs at Home or Hospitalized | 1.315 | <0.001 | 1.130 | 0.017 | 1.313 | <0.001 | 1.132 | 0.018 |
| Recipient Black vs not Black | 0.938 | 0.587 | 1.310 | <0.001 | 0.998 | 0.987 | 1.336 | <0.001 |
| Previous Heart Transplant: Yes vs No | 2.397 | <0.001 | 3.312 | <0.001 | 2.352 | <0.001 | 3.368 | <0.001 |
| On Ventilator at Transplant: Yes vs No | 2.402 | <0.001 | 1.999 | <0.001 | 2.404 | <0.001 | 2.034 | <0.001 |
| On VAD at Transplant: Yes vs No | 1.758 | <0.001 | 1.328 | 0.031 | 1.612 | 0.006 | 1.300 | 0.059 |
| On IABP at Transplant: Yes vs No | 1.346 | 0.013 | 1.179 | 0.084 | 1.338 | 0.020 | 1.166 | 0.118 |
| Coronary Heart Disease vs Cardiomyopathy | 1.168 | 0.051 | 1.078 | 0.173 | 1.181 | 0.043 | 1.081 | 0.170 |
| Congenital Diagnosis vs Cardiomyopathy | 2.012 | <0.001 | 1.339 | 0.019 | 1.928 | <0.001 | 1.364 | 0.016 |
| Valvular Heart Disease vs Cardiomyopathy | 1.504 | 0.012 | 1.207 | 0.126 | 1.498 | 0.017 | 1.235 | 0.092 |
| Other Heart Disease [2] vs Cardiomyopathy | 1.714 | 0.021 | 1.154 | 0.449 | 1.490 | 0.121 | 1.098 | 0.639 |
| Transplant year 1993-1994 vs 1988-1992 | 0.895 | 0.156 | 0.868 | 0.013 | 0.888 | 0.143 | 0.875 | 0.022 |

Notes:

[1] Odds ratios for continuous covariates (donor age, recipient age and cold ischemic time) do not have a linear relationship. The odds ratios presented in this table are 10 years (donor and recipient age) or 15 minutes (cold ischemic time) unit increases from the mean of each covariate. The mean donor age was 26. The mean recipient age was 45. The mean cold ischemic times was 163 minutes.

[2] See Table VI-8 for a listing of Other heart diagnoses.

where 60 is the amount of increase in minutes and 15 minutes is the per unit of increase; 0.0296 corresponds to the coefficient of cold ischemic time per 15 minute difference (see Table VI-12 for coefficients). Therefore, the increase in the odds of death or graft failure is (1.12-1)×100%=12%. For some variables such as recipient age index, it is necessary to add a quadratic term. For more details on calculating odds ratios for continuous variables, refer to the section on *Odds Ratios* in the *Technical Methods* chapter of the *Executive Summary*.

Short Term Graft and Patient Survival

The characteristics with the strongest impact on short term graft and patient survival were, having a previous heart transplant, being on a ventilator or VAD at time of transplant, and having a congenital diagnosis. The odds of 1 year graft failure was 231% higher if the transplant was a repeat transplant. If a ventilator was used at time of transplant, then the odds of 1 year mortality was 103% higher than if a ventilator was not being used at time of transplant.

## G. LONG TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

In this report, *long term* survival analyses were developed separately from the short term survival analyses. Because this narrative focuses on conditional 3 year survival (survival at 3 years for grafts or patients surviving at least 1 year post-transplant), only conditional 3 year survival data are presented in this text. Both conditional and unconditional 3 year survival rates are provided in the tables for each transplant program presented in each organ specific volume.

The conditional 3 year survival analyses assesses donor and recipient characteristics that are independent of those limited to the first year (e.g., surgical complications). The impact of each donor and recipient characteristic on graft and patient long term survival is listed in Table VI-10.

**Table VI-10. Impact of Donor and Recipient Characteristics on Long Term Graft and Patient Survival -- Heart Transplants**

| Long Term Risk Characteristics | Graft | | Patient | |
|---|---|---|---|---|
| | Odds Ratio | P-value | Odds Ratio | P-value |
| **Donor Age 36 vs 26**[1] | 1.144 | <0.001 | 1.126 | 0.003 |
| **Donor Hispanic vs White, Black** | 1.544 | 0.001 | 1.515 | 0.003 |
| **Donor Asian, Other vs White, Black** | 1.622 | 0.116 | 1.734 | 0.074 |
| **Recipient Age 55 vs 45**[1] | 1.021 | 0.640 | 1.041 | 0.387 |
| **Previous Heart Transplant: Yes vs No** | 1.956 | 0.005 | 2.113 | 0.007 |
| **Recipient Black vs White** | 1.691 | <0.001 | 1.725 | <0.001 |
| **Recipient Hispanic vs White** | 1.491 | 0.030 | 1.522 | 0.025 |
| **Recipient Asian, Other vs White** | 1.654 | 0.025 | 1.561 | 0.060 |

Notes:

[1] Odds ratios for continuous covariates (donor age, recipient age) do not have a linear relationship. The odds ratios presented in this table are 10 unit increases from the mean of each covariate. The mean donor age was 26 and mean recipient age was 45.

The following characteristics and reference groups were used for ***long term graft and patient*** survival:

- Mean Donor Age -- 26 years
- Donor Race -- White, Black
- Previous Heart Transplant -- no
- Mean Recipient Age -- 45 years
- Recipient Race -- White

**Graft and Patient Survival**

The characteristics with the strongest impact on long term graft and patient survival were, having a previous heart transplant, donor race and recipient race. The odds of conditional 3 year patient death was 111% higher if the transplant was a repeat transplant. Blacks, Hispanics and recipients of other Races had worse long term graft and patient survival than did White recipients. Recipients of hearts from Hispanic donors had at 54% higher odds of graft failure than did recipients of hearts from White or Black donors.

## H. COMPARISON BETWEEN SHORT TERM AND LONG TERM CHARACTERISTICS

The majority of the donor and recipient characteristics that had a strong impact on short term graft survival did not appear to have a strong impact on long term graft survival. Some exceptions were donor and recipient race and age and if it was a first or repeat transplant.

Medical condition at transplant and diagnosis had a strong impact for short term survival, but were not significant predictors for long term survival.

## I. STATISTICAL METHODS AND MODELS

***This section provides a brief summary of the statistical methods used to determine survival rates for heart transplants, both nationally and at each transplant program. It is not necessary to read this section in order to utilize the rest of the report. For additional statistical details, please see the Technical Methods chapter in the Executive Summary.***

**Model Significance -- $R^2$**

The conclusion that there is a "center effect" in heart transplantation often is based on the observation that actual survival rates vary considerably among heart transplant programs. However, in reality, only part of the variability can be attributed to the quality of the program (the so called "center effect"); the rest can be attributed to the differences in donor and recipient characteristics among transplant programs. The degree to which the variability in actual survival rates can be attributed to the specific donor and recipient characteristics in each analysis appears in Table VI-11.

In the table, the values in the column labeled $R^2$ estimate the percentage of variability in the actual survival rates that can be attributed to the covariates in each analysis. *The higher the percentage, the better the analysis explained the individual program outcomes, based on the characteristics examined.* Theoretically, if an analysis contained every covariate that affected survival outcomes, and there were no differences in quality among programs (i.e., no "center effect"), then $R^2$ would equal 100%. In practice, we can never capture every factor that affects outcomes, and it is likely that real differences among programs do exist. This means that any unexplained variation can probably be attributed to a combination of true center effect and covariates not considered in this study. (For details on the $R^2$ calculation, refer to the *Model Significance* section in the *Technical Methods* chapter of the *Executive Summary*. )

The value of $R^2$ estimated from analyses in the 1994 Report was compared to the value of the $R^2$ analyses in the 1997 Report. Note that these analyses are not *directly* comparable since each was used with a different cohort of transplants. Nevertheless, the extensive characteristics considered in the 1997 Report appear to explain more of the variability in the actual survival rates. Despite the refinements in the 1997 Report, as compared to the 1994 Report, much of the variation in actual survival rates among the 161 transplant programs in the study remains unexplained by the analyses. This suggests that much of the risk involved in transplantation is due to characteristics not described in this report.

Table VI-11. Heart Model $R^2$: Comparison of the 1994 and 1997 Reports

| Outcome | Time Point | Report Year | Number of Covariates | $R^2$ |
|---|---|---|---|---|
| Graft Model $R^2$ | 1 Month | 1997<br>1994 | 22<br>15 | 26<br>19 |
| | 1 Year | 1997<br>1994 | 22<br>15 | 36<br>29 |
| | Cond. 3 Year* | 1997<br>1994 | 8<br>NA | 8<br>NA |
| Patient Model $R^2$ | 1 Month | 1997<br>1994 | 22<br>15 | 25<br>18 |
| | 1 Year | 1997<br>1994 | 22<br>15 | 36<br>33 |
| | Cond. 3 Year* | 1997<br>1994 | 8<br>NA | 9<br>NA |

* Conditional 3 year analysis was not performed in the 1994 report.

Estimated Coefficients and Standard Errors from the Logistic Regression Models

Tables VI-12 and VI-13 list the coefficients and the standard errors of the coefficients at each time point for all of the donor and recipient characteristics used in the logistic regression models. Each coefficient is reported on the logistic scale and represents the $\log_e$ odds of graft failure or the $\log_e$ odds of patient mortality for the corresponding characteristic at the specified time after transplant. The adjusted odds ratio on the probability scale may be obtained by applying the exponential function to the coefficient. For further details, see the *Odds Ratios* section in the *Technical Methods* chapter of the *Executive Summary*.

Expected Heart Transplant Survival Rates

Table VI-14 shows the 1 year *expected graft* survival rates for heart transplants for a given set of donor and recipient characteristics; Table VI-15 shows the 1 year *expected patient* survival rates. These rates were determined using the following characteristics: recipient age, diagnosis, gender and primary or repeat transplant. For these analyses, all other characteristics were set to the values for the reference groups, with the exception of the year of transplant. The complete list of reference groups is shown on page 94.

For example, in Table VI-14, the expected 1 year graft survival for a 40 year old male recipient of a first cadaveric heart transplant with coronary heart disease was 90%. In contrast, the expected 1 year graft survival for a female heart recipient of the same age and disease was 89%.

## J. SUMMARY

Study Period

The 1997 Report was based on 12,627 heart transplants performed in 12,428 patients between January 1, 1988, and April 30, 1994, from 161 transplant programs in the United States. In order to assess changes within transplant programs over time, the data were divided into 2 eras. The first era included transplants performed from January 1, 1988, through April 30, 1992; the second era covered the two year time period from May 1, 1992, through April 30, 1994.

**Table VI-12. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Short Term Heart Transplant Survival**

| Short Term Risk Characteristics | Graft | | | | Patient | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| **Intercept** | -3.2272 | 0.087 | -2.0973 | 0.060 | -3.2949 | 0.091 | -2.1587 | 0.061 |
| **Donor Age - Linear (per 10 years)[1,2]** | 0.0868 | 0.038 | 0.0848 | 0.027 | 0.0894 | 0.040 | 0.0830 | 0.028 |
| **Donor Age - Quadratic (per 10 years)[1,2]** | 0.0693 | 0.020 | 0.0478 | 0.015 | 0.0653 | 0.020 | 0.0494 | 0.015 |
| **Donor Black vs White** | -0.1258 | 0.115 | 0.1393 | 0.078 | -0.1220 | 0.119 | 0.1432 | 0.080 |
| **Donor Hispanic vs White** | 0.1320 | 0.111 | 0.2436 | 0.079 | 0.1562 | 0.114 | 0.2404 | 0.081 |
| **Donor Asian, Other vs White** | -0.1775 | 0.282 | 0.3808 | 0.179 | -0.1569 | 0.294 | 0.3942 | 0.184 |
| **Donor Female vs Male** | 0.2346 | 0.071 | 0.1581 | 0.052 | 0.2084 | 0.074 | 0.1432 | 0.054 |
| **Cold Ischemic Time (per 15 min)[1,2]** | 0.0296 | 0.007 | 0.0217 | 0.006 | 0.0288 | 0.008 | 0.0204 | 0.006 |
| **Recipient Age - Linear (per 10 years)[1,2]** | 0.1116 | 0.032 | 0.1404 | 0.023 | 0.1296 | 0.033 | 0.1577 | 0.023 |
| **Recipient Age-Quadratic(per 10 years)[1,2]** | 0.0453 | 0.014 | 0.0530 | 0.010 | 0.0538 | 0.015 | 0.0557 | 0.011 |
| **Recipient Age <=1** | -0.4000 | 0.217 | -0.0567 | 0.173 | -0.3563 | 0.224 | -0.0426 | 0.178 |
| **Recipient Female vs Male** | 0.2493 | 0.079 | 0.0948 | 0.059 | 0.2539 | 0.082 | 0.0906 | 0.061 |
| **Recipient in ICU vs at Home or Hospitalized** | 0.2740 | 0.073 | 0.1219 | 0.051 | 0.2724 | 0.075 | 0.1240 | 0.052 |
| **Recipient Black vs Not Black** | -0.0644 | 0.118 | 0.2703 | 0.079 | -0.0098 | 0.121 | 0.2897 | 0.081 |
| **Previous Heart Transplant: Yes vs No** | 0.8741 | 0.147 | 1.1976 | 0.117 | 0.8553 | 0.183 | 1.2143 | 0.140 |
| **On Ventilator at Transplant: Yes vs No** | 0.8762 | 0.116 | 0.6924 | 0.098 | 0.8770 | 0.121 | 0.7099 | 0.102 |
| **On VAD at Transplant: Yes vs No** | 0.5641 | 0.158 | 0.2838 | 0.132 | 0.4773 | 0.172 | 0.2621 | 0.139 |
| **On IABP at Transplant: Yes vs No** | 0.2970 | 0.120 | 0.1644 | 0.095 | 0.2909 | 0.125 | 0.1534 | 0.098 |
| **Coronary Heart Disease vs Cardiomyopathy** | 0.1552 | 0.079 | 0.0755 | 0.055 | 0.1661 | 0.082 | 0.0778 | 0.057 |
| **Congenital Heart Disease vs Cardiomyopathy** | 0.6991 | 0.159 | 0.2919 | 0.124 | 0.6566 | 0.166 | 0.3104 | 0.129 |
| **Valvular Heart Disease vs Cardiomyopathy** | 0.4078 | 0.163 | 0.1878 | 0.123 | 0.4038 | 0.169 | 0.2111 | 0.125 |
| **Other Heart Disease vs Cardiomyopathy** | 0.5388 | 0.234 | 0.1430 | 0.189 | 0.3991 | 0.257 | 0.0931 | 0.199 |
| **Transplant year 1993-1994 vs 1988-1992** | -0.1113 | 0.078 | -0.1411 | 0.057 | -0.1188 | 0.081 | -0.1335 | 0.058 |

Notes:

[1] In the analysis, the continuous covariates (donor and recipient age, cold ischemic time) were centered at their mean. The mean donor age was 26. The mean cold ischemic time was 163 minutes. The mean donor age was 45.

[2] Modeling the continuous covariates with a liner and quadratic term (the square of the linear term) is necessary due to the relationship between the covariate and the odds of graft failure or death.

Table VI-13. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Long Term Heart Transplant Survival

| Long Term Characteristics | Graft | | Patient | |
|---|---|---|---|---|
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| Intercept | -2.4229 | 0.063 | -2.4838 | 0.065 |
| Donor Age (per 10 years) [1,2] | 0.1348 | 0.038 | 0.1185 | 0.034 |
| Donor Hispanic vs White, Black | 0.4341 | 0.134 | 0.4155 | 0.138 |
| Donor Asian, Other vs White, Black | 0.4839 | 0.308 | 0.5505 | 0.308 |
| Recipient Age - Linear (per 10 years)[1,2] | -0.0018 | 0.038 | 0.0143 | 0.039 |
| Recipient Age - Quadratic (per 10 years)[1,2] | 0.0229 | 0.014 | 0.0256 | 0.014 |
| Previous Heart Transplant: Yes vs No | 0.6711 | 0.241 | 0.7483 | 0.277 |
| Recipient Black vs White | 0.5251 | 0.130 | 0.5455 | 0.132 |
| Recipient Hispanic vs White | 0.3997 | 0.184 | 0.4200 | 0.188 |
| Recipient Asian, Other vs White | 0.5031 | 0.224 | 0.4453 | 0.236 |

Notes:

[1] In the analysis, the continuous covariates (donor and recipient age, cold ischemic time) were centered at their mean. The mean donor age was 26. The mean cold ischemic time was 163 minutes. The mean donor age was 45.

[2] Modeling the continuous covariates with a liner and quadratic term (the square of the linear term) is necessary due to the relationship between the covariate and the odds of graft failure or death.

## Survival Rates

Survival rates were computed at 1 month, 1 year, and 3 years, both nationally and for each transplant program. Three year survival was determined in two ways: (1) conditional 3 year survival (i.e., survival at 3 years for those who survived at least 1 year post-transplant), and (2) unconditional 3 year survival. The emphasis on long term survival in this chapter is on the conditional 3-year survival rates because the conditional 3-year analysis provides an assessment of characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

The national graft and patient survival rates and completeness of follow-up at 1 month, 1 year, and conditional 3 years are shown in Tables VI-1 and VI-2 The percent of programs with graft and patient follow-up data at 1 year was more than 98%; at conditional 3 years the percent of programs with follow-up data was also 98%.

There was a marked increase in the number of heart transplants from Era 1 to Era 2. As demonstrated in Table VI-16, the number of heart transplants increased by 17% from an average of 157 transplants per month in Era 1 to 185 transplants per month in Era 2.

For the majority of transplant programs, the difference between actual and expected survival rates was not statistically significant (See Figures VI-1 and VI-3). In general, large differences (either higher or lower) were nearly always found among programs that reported relatively few transplants (see Figure VI-2). Therefore, when evaluating survival rates for a program, it is also important to consider the number of transplants performed there.

**Table VI-14. Expected U.S. 1 Year Graft Survival Rates -- Heart Transplants Stratified by Recipient Age, Diagnosis, Gender, and Primary or Repeat Transplant**

| Age | Diagnosis | Male | | Female | |
|---|---|---|---|---|---|
| | | Primary | Repeat | Primary | Repeat |
| 5 | Cardiomyopathy | 87.6 | 68.0 | 86.5 | 65.9 |
| | Coronary Heart Disease | 86.7 | 66.3 | 85.6 | 64.2 |
| | Congenital Disease | 84.0 | 61.3 | 82.7 | 59.1 |
| | Valvular Disease | 85.4 | 63.8 | 84.1 | 61.6 |
| | Other Disease | 85.9 | 64.8 | 84.7 | 62.6 |
| 25 | Cardiomyopathy | 90.9 | 75.2 | 90.1 | 73.4 |
| | Coronary Heart Disease | 90.3 | 73.8 | 89.4 | 71.9 |
| | Congenital Disease | 88.2 | 69.4 | 87.2 | 67.3 |
| | Valvular Disease | 89.3 | 71.5 | 88.3 | 69.6 |
| | Other Disease | 89.7 | 72.4 | 88.8 | 70.5 |
| 40 | Cardiomyopathy | 90.8 | 75.0 | 90.0 | 73.2 |
| | Coronary Heart Disease | 90.2 | 73.5 | 89.3 | 71.7 |
| | Congenital Disease | 88.1 | 69.1 | 87.1 | 67.1 |
| | Valvular Disease | 89.2 | 71.3 | 88.2 | 69.3 |
| | Other Disease | 89.6 | 72.2 | 88.7 | 70.3 |
| 50 | Cardiomyopathy | 89.6 | 72.3 | 88.7 | 70.3 |
| | Coronary Heart Disease | 88.9 | 70.7 | 87.9 | 68.7 |
| | Congenital Disease | 86.6 | 66.0 | 85.4 | 63.9 |
| | Valvular Disease | 87.7 | 68.3 | 86.7 | 66.3 |
| | Other Disease | 88.2 | 69.3 | 87.2 | 67.3 |
| 60 | Cardiomyopathy | 87.1 | 67.1 | 86.0 | 64.9 |
| | Coronary Heart Disease | 86.2 | 65.4 | 85.0 | 63.2 |
| | Congenital Disease | 83.4 | 60.3 | 82.1 | 58.0 |
| | Valvular Disease | 84.8 | 62.8 | 83.6 | 60.5 |
| | Other Disease | 85.4 | 63.8 | 84.2 | 61.6 |

**Table V-15. Expected U.S. 1 Year Patient Survival Rates -- Heart Transplants Stratified by Recipient Age, Diagnosis, Gender, and Primary or Repeat Transplant**

| Age | Diagnosis | Male | | Female | |
|---|---|---|---|---|---|
| | | Primary | Repeat | Primary | Repeat |
| 5 | Cardiomyopathy | 88.4 | 69.4 | 87.5 | 67.4 |
| | Coronary Heart Disease | 87.6 | 67.7 | 86.6 | 65.7 |
| | Congenital Disease | 84.8 | 62.4 | 83.6 | 60.3 |
| | Valvular Disease | 86.1 | 64.7 | 84.9 | 62.6 |
| | Other Disease | 87.4 | 67.4 | 86.4 | 65.3 |
| 25 | Cardiomyopathy | 91.6 | 76.3 | 90.8 | 74.6 |
| | Coronary Heart Disease | 90.9 | 74.9 | 90.2 | 73.1 |
| | Congenital Disease | 88.8 | 70.3 | 87.9 | 68.3 |
| | Valvular Disease | 89.8 | 72.3 | 88.9 | 70.5 |
| | Other Disease | 90.8 | 74.6 | 90.0 | 72.8 |
| 40 | Cardiomyopathy | 91.3 | 75.8 | 90.6 | 74.1 |
| | Coronary Heart Disease | 90.7 | 74.4 | 89.9 | 72.6 |
| | Congenital Disease | 88.6 | 69.7 | 87.6 | 67.7 |
| | Valvular Disease | 89.5 | 71.7 | 88.6 | 69.9 |
| | Other Disease | 90.6 | 74.1 | 89.8 | 72.3 |
| 50 | Cardiomyopathy | 90.0 | 72.8 | 89.2 | 71.0 |
| | Coronary Heart Disease | 89.3 | 71.2 | 88.4 | 69.4 |
| | Congenital Disease | 86.9 | 66.3 | 85.8 | 64.2 |
| | Valvular Disease | 88.0 | 68.4 | 87.0 | 66.4 |
| | Other Disease | 89.2 | 70.9 | 88.2 | 69.0 |
| 60 | Cardiomyopathy | 87.3 | 67.2 | 86.3 | 65.1 |
| | Coronary Heart Disease | 86.4 | 65.4 | 85.3 | 63.4 |
| | Congenital Disease | 83.5 | 60.0 | 82.2 | 57.8 |
| | Valvular Disease | 84.8 | 62.4 | 83.6 | 60.2 |
| | Other Disease | 86.3 | 65.1 | 85.2 | 63.0 |

**Table VI-16. Comparison of 1 Month and 1 Year Actual Survival Rates Between Eras**

| | 1 Month | | 1 Year | |
|---|---|---|---|---|
| | Era 1 | Era 2 | Era 1 | Era 2 |
| Graft Survival (%) | 91.6% | 91.5% | 81.5% | 81.9% |
| Average No. of Transplants/Month | 157 | 185 | 158 | 185 |
| Patient Survival (%) | 92.1% | 92.0% | 82.4% | 82.8% |
| Average No. of Patients/Month | 155 | 183 | 155 | 184 |

**Differences Between Short Term and Long Term Characteristics**

The 1997 Report includes an extensive list of characteristics that have a significant impact on both short and long term graft and patient survival.

Characteristics with the strongest impact on *short term survival* were:

- Recipient received a previous heart transplant
- Recipient on ventilator at transplant
- Recipient had a congenital heart diagnosis
- Year of transplant was 1993 or 1994

Characteristics with the strongest impact on *long term survival* were:

- Recipient received a previous heart transplant
- Donor was Hispanic
- Recipient was Black or Hispanic

## K. FINAL WORDS

The purpose of this report is to provide updated information on survival outcomes both nationally and at specific transplant programs, and to enhance the awareness of program performance in the U.S. However, the assessment of a transplant program should not be based solely on the survival rates provided in this report. Some of the other important factors to consider are the experience of the transplant team, support personnel, the cost of the procedure, and the quality and location of post-transplant services.

# VII. LUNG CHAPTER

# VII. LUNG TRANSPLANT SURVIVAL RATES

*For the Summary of this chapter, see page 119. For definitions of any terms used here, please refer to the User's Guide in the Lung volume.*

## A. INTRODUCTION

This report of lung transplant survival rates is based upon verified Scientific Registry data for 2,135 transplants involving 2,079 patients from 75 lung transplant programs in the United States. Each program reporting at least one lung transplant between January 1, 1988, and April 30, 1994, was included. Multi-organ and living donor transplants were excluded.

Short term survival is defined as survival at 1 month and 1 year post-transplant. Short term survival rates are based on all transplants in the study for which there are follow-up data.

Long term survival is defined in two ways:

- unconditional survival at 3 years post-transplant, and
- survival at 3 years post-transplant for those who survived at least 1 year, referred to as **conditional 3 year survival.**

The long term survival rates are based on all transplants between January 1, 1988, and April 30, 1992, for which there are follow-up data. This cohort was chosen to ensure that the maximum number of transplants with follow-up data was used to determine long term survival rates. Please note this report emphasizes *conditional* 3-year survival rates. This is because the conditional 3-year analysis assesses characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

## B. COMPLETENESS OF FOLLOW-UP DATA AND OVERALL GRAFT AND PATIENT SURVIVAL RATES

For graft survival, completeness of follow-up data and overall actual survival rates at each time point are shown in Table VII-1; patient survival data are shown in Table VII-2.

Patient (graft) follow-up data were considered complete when:

- the patient was alive (lung was functioning) and the duration of survival (function) was equal to or exceeded the specified time after transplant (i.e., 1 month, 1 or 3 years), or
- the patient died (lung failed) and a valid date of death (failure) was reported.

The percentages of complete follow-up data ranged from a low of 95.2% for the conditional 3 year time point to a high of 99.5% for the 1 month time point. Patient survival rates are similar to graft survival rates since patient death follows graft failure unless the patient is retransplanted.

Overall survival rates also are presented in the tables. Patient survival rates are comparable to graft survival rates because patient death usually follows graft failure. If a graft had incomplete follow-up data, the observation was weighted to account for the time during which the graft was known to be functioning. Therefore, the actual graft survival rate reflects the weighted proportion of grafts functioning at the specified time interval. Patient survival rates were computed in a similar way (see the *Technical Methods* chapter of the *Executive Summary*).

In the cohort of transplants (1/1/88 - 4/30/92) used to compute conditional 3 year survival rates, patients (grafts) who did not survive to 1 year after transplant were excluded from the analyses. Therefore, the total number of patients (grafts) for the conditional 3 year analysis was less than that for the 1 month and 1 year analyses.

Please note that the conditional 3 year graft and patient survival rates in Tables VII-1 and VII-2 may be higher than the 1 year graft survival rates. This is possible because the conditional 3 year survival rate is the 3 year survival rate for patients (grafts) who (which) survived at least 1 year post-transplant.

For example: Program A performed a total of five transplants between 1/1/88 and 4/30/92. Two of the lungs failed prior to 1 year post-transplant and the remaining three lungs survived to 3 years after

transplant. In this example, Program A has a 1 year graft survival rate of 60% (3 out of 5 lungs were functioning at 1 year post-transplant). However, the conditional 3 year survival rate for Program A is 100% because all three lungs that were functioning at 1 year after transplant also were functioning at 3 years post-transplant. The same calculations are used for patient survival. See the *Technical Methods* chapter of the *Executive Summary* for more specific definitions of follow-up data and the calculations for actual graft and patient survival.

Overall Graft and Patient Survival Rates by Era

In this report, short term survival also is reported by era. Separate eras were used to determine whether there were any improvements over time in the short term survival rates. Era 1 is defined as all transplants occurring between January 1, 1988, and April 30, 1992; Era 2 includes all transplants occurring between May 1, 1992, and April 30, 1994. The overall graft and patient survival rates by era are presented in the last two columns of Table VII-1 and Table VII-2, respectively. The results demonstrate substantial improvement for both graft and patient survival rates over time.

## C. GRAFT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

For each transplant program, actual and expected survival rates were calculated at 1 month, 1 year, and 3 years conditional on survival at 1 year. Survival rates at each time point were determined using a specific cohort of transplants (shown in Tables VII-1 and VII-2). Expected survival rates were determined for each transplant program based on its specific patient and donor characteristics. These expected outcomes were statistically adjusted for many important prognostic variables, or covariates, that were used in the survival analysis. In other words, they take into account many different characteristics that affect survival. For example: if Program A transplanted many more "high risk" recipients than Program B, then Program A would have a lower *expected* survival rate than Program B.

**Table VII-1. Completeness of Graft Follow-Up Data and Actual Survival Rates for Lung Transplants**

| Time | Cohort | Number of Transplants | Percent with Follow-Up Data | Graft Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 1 Month | 1/1/88 - 4/30/94 | 2,135 | 99.5 | 86.8 | 83.5 | 89.3 |
| 1 Year | 1/1/88 - 4/30/94 | 2,135 | 98.7 | 70.4 | 66.6 | 73.4 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 608 | 95.4 | 74.7* | 74.7* | N.A.* |

**Table VII-2. Completeness of Patient Follow-Up Data and Actual Survival Rates for Lung Transplants**

| Time | Cohort | Number of Patients | Percent with Follow-Up Data | Patient Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 1 Month | 1/1/88 - 4/30/94 | 2,079 | 99.5 | 87.7 | 84.5 | 90.0 |
| 1 Year | 1/1/88 - 4/30/94 | 2,079 | 98.6 | 71.9 | 68.4 | 74.5 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 606 | 95.2 | 75.9* | 75.9* | N.A.* |

* The cohort used to determine the overall conditional 3 year survival rate is the same as the Era 1 cohort. Therefore, the overall conditional 3 year survival rates are identical to the conditional 3 year survival rates for Era 1. There is no conditional 3 year survival rate calculated for Era 2 due to insufficient follow-up data on patients who received transplants in Era 2.

If a program's *actual* survival rate was *greater* than its expected survival rate, this means that the program's actual results were higher than the national results for transplants *with the same donor and recipient characteristics*. If a program's *actual* survival rate was *less than* its expected survival rate, this means that the program's actual results were lower than the national results for transplants *with the same donor and recipient characteristics*. The difference between the actual and expected rate may have occurred by chance and, therefore, may not be statistically significant. Furthermore, even a statistically significant difference, one that most likely did not occur by chance, may not be clinically significant (i.e., medically important). A formal description of the methods used to determine actual and expected survival rates appears in the *Technical Methods* chapter of the *Executive Summary*.

Table VII-3 shows the percentages of lung transplant programs by category of graft survival rates, both for actual and expected survival. The majority of the transplant programs had actual survival rates greater than 70% at all time points. At 1 month, 43% of programs had actual survival rates greater than 90%. At 1 year, this fell to 11%. However, this percentage increased to 33% for the conditional 3 year survival rates. The distribution of the expected survival rates shows a similar trend. The results indicate that there are more programs with high survival rates at the conditional 3 year time point than there are at the 1 year time point. *This is because the most critical period of time for graft survival is the first year post-transplant.* Those who survive the first year are more likely to survive 3 years post-transplant.

The percentages of programs by short term graft survival rates and eras, both for actual and expected survival, are summarized in Table VII-4. The results demonstrate a substantial improvement in graft survival over time because a greater percentage of programs had actual survival rates higher than 80% in Era 2.

**Differences in Actual and Expected Survival Rates**

For most programs, the difference between the actual survival rate and the expected survival rate was not statistically significant. Figure VII-1 shows the percentages of programs whose actual graft survival rates were either above, not significantly different from, or below expected graft survival rates at three time points. Actual survival rates shown in the figure to be either greater than or less than expected survival rates were statistically significant. Overall, there were more programs that fell significantly below expected results than programs that were significantly above expected results. However, for the majority of the transplant programs, the difference in actual and expected graft survival was not statistically significant and varied little across time points.

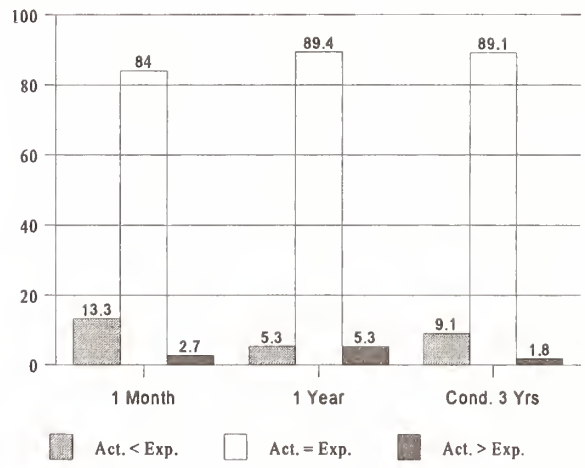
**Table VII-3. Percentages of Lung Transplant Programs by Graft Survival Rates**

| Graft Survival Rates (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 1 Month (n=75) | 1 Year (n=75) | Cond. 3 Yrs (n=55) | 1 Month (n=75) | 1 Year (n=75) | Cond. 3 Yrs (n=55) |
| 0-60 | 9.3 | 28.0 | 21.8 | 0.0 | 8.0 | 1.8 |
| >60-70 | 8.0 | 20.0 | 18.2 | 2.7 | 29.3 | 18.2 |
| >70-80 | 10.7 | 25.3 | 12.7 | 5.3 | 62.7 | 70.9 |
| >80-90 | 29.3 | 16.0 | 14.6 | 68.0 | 0.0 | 9.1 |
| >90-100 | 42.7 | 10.7 | 32.7 | 24.0 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Table VII-4. Percentages of Lung Transplant Programs by Graft Survival Rates and Era**

| Graft Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Era 1 (n=65) | Era 2 (n=67) | Era 1 (n=65) | Era 2 (n=67) | Era 1 (n=65) | Era 2 (n=67) | Era 1 (n=65) | Era 2 (n=67) |
| 0-60 | 21.5 | 4.5 | 46.2 | 22.4 | 0.0 | 0.0 | 16.9 | 3.0 |
| >60-70 | 3.1 | 3.0 | 13.8 | 17.9 | 6.2 | 0.0 | 58.5 | 16.4 |
| >70-80 | 20.0 | 13.4 | 16.9 | 29.9 | 18.5 | 0.0 | 24.6 | 79.1 |
| >80-90 | 12.3 | 17.9 | 4.6 | 10.4 | 64.6 | 47.8 | 0.0 | 1.5 |
| >90-100 | 43.1 | 61.2 | 18.5 | 19.4 | 10.8 | 52.2 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

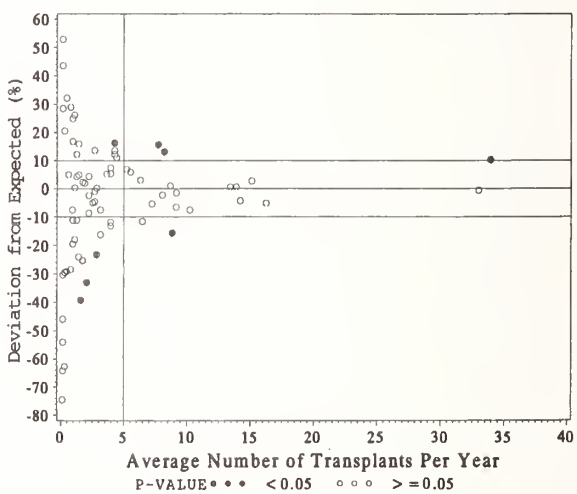
**Figure VII-1. Percentages of Lung Transplant Programs with Actual Graft Survival Rates Above, Below, or Equal to Expected Survival Rates. ***




* Actual survival rates above or below expected survival rates are statistically significant and varied little across time points.

At all time points, the larger differences in actual and expected rates were nearly always seen in programs that reported relatively few transplants during the period. This occurs because programs that do not perform many transplants tend to have highly variable outcomes. To illustrate this, Figure VII-2 shows a scatter plot of the average number of transplants per year (transplant volume) versus the difference in 1 year actual and expected graft survival. Nearly all differences greater than 10% (either positive or negative) are found among transplant programs which perform very few transplants per year.

**Figure VII-2. Lung Transplant Volume vs Difference in Actual and Expected 1 Year Graft Survival Rates.**




*Please note that actual survival rates which differ from expected survival rates are not always statistically significant and even statistically significant differences may not be clinically significant.*

## D. PATIENT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

The percentages of programs by patient survival rates for both actual and expected survival are shown in Table VII-5; the percentages of programs by survival rates and eras are shown in Table VII-6. As with graft survival, the outcomes in Era 2 were better than in Era 1.

### Differences in Actual and Expected Survival Rates

Overall, there were more programs that fell significantly below expected results than above expected results (see Figure VII-3). However, for the majority of transplant programs, the difference in actual and expected patient survival was not statistically significant and varied little across time points.

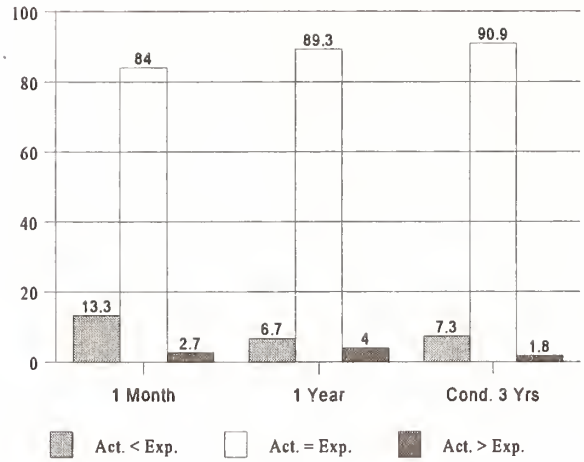
**Table VII-5. Percentages of Lung Transplant Programs by Patient Survival Rates**

| Patient Survival Rates (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 1 Month (n=75) | 1 Year (n=75) | Cond. 3 Yrs (n=55) | 1 Month (n=75) | 1 Year (n=75) | Cond. 3 Yrs (n=55) |
| 0-70 | 16.0 | 46.7 | 40.0 | 2.7 | 29.3 | 16.4 |
| >70-80 | 12.0 | 25.3 | 10.9 | 5.3 | 68.0 | 74.5 |
| >80-90 | 24.0 | 17.3 | 14.6 | 60.0 | 2.7 | 9.1 |
| >90-95 | 18.7 | 0.0 | 1.8 | 32.0 | 0.0 | 0.0 |
| >95-100 | 29.3 | 10.7 | 32.7 | 0.0 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Table VII-6. Percentages of Lung Transplant Programs by Patient Survival Rates and Era**

| Patient Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Era 1 (n=65) | Era 2 (n=67) | Era 1 (n=65) | Era 2 (n=67) | Era 1 (n=65) | Era 2 (n=67) | Era 1 (n=65) | Era 2 (n=67) |
| 0-70 | 23.1 | 6.0 | 58.4 | 38.8 | 6.2 | 0.0 | 66.2 | 14.9 |
| >70-80 | 16.9 | 14.9 | 18.5 | 28.4 | 13.8 | 0.0 | 33.8 | 80.6 |
| >80-90 | 12.3 | 17.9 | 3.1 | 11.9 | 66.2 | 32.8 | 0.0 | 4.5 |
| >90-95 | 10.8 | 17.9 | 0.0 | 6.0 | 13.8 | 67.2 | 0.0 | 0.0 |
| >95-100 | 36.9 | 43.3 | 20.0 | 14.9 | 0.0 | 0.0 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Figure VII-3. Percentages of Lung Transplant Programs with Actual Patient Survival Rates Above, Below, or Equal to Expected Survival Rates. ***




* Actual survival rates above or below expected survival rates are statistically significant and varied little across time points

## E. NATIONAL DISTRIBUTION OF DONOR AND RECIPIENT CHARACTERISTICS

The national distribution of donor and recipient characteristics for lung transplants, presented in percentages, is shown in Table VII-7. Each of these donor and recipient characteristics was included in the analyses for graft or patient survival, and used to determine an expected survival rate for each transplant. The transplant types were evenly divided among single left lung transplants (34%), single right lung transplants (33%) and double lung transplants (33%). The majority of lungs transplanted were recovered from white male donors between the ages of 18 and 35 (52%). Most of the lung recipients were white males greater than 50 years of age (41%), and were neither hospitalized (85%) nor on ventilator (94%) prior to transplant. Of the 2,135 lung transplants performed, only 3% were due to repeat transplants. The most common disease diagnoses were Chronic Obstructive Pulmonary Disease (COPD) and Emphysema (33%), followed by Cystic and Idiopathic Fibrosis (27%). In general, cold ischemic time for single lung transplants was shorter than double lung transplants.

### Donor and Recipient Trends

There were 1,216 lung transplants performed in the last two years of the study period (Era 2); this represents a 30% increase from the 919 transplants performed in the previous four years (Era 1).

National donor and recipient characteristics changed slightly between Era 1 and Era 2. There was a slight increase in young donors in Era 2, and the percent of donors age 50 and older almost doubled (2.6% to 5.0%). There was also a 3% increase in minority donors. Transplant recipients were older in the second era; those over age 49 comprised 46% of recipients in Era 2 as compared to 34% in Era 1. There were fewer recipients in the ICU at the time of transplant in Era 2 than in Era 1. COPD and Emphysema accounted for 26% of the diseases in Era 1 and increased to 39% in Era 2. Alpha-1-Antitrypsin Deficiency and Primary Pulmonary Hypertension decreased from 17% to 12% and from 13% to 10%, respectively. Also, cold ischemic time increased from Era 1 to Era 2.

Despite more older donors and older recipients in Era 2, the national survival rates at 1 year post transplant improved from Era 1 to Era 2 (See Tables VII-1 and VII-2 on page 108).

## F. SHORT TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

To determine the expected survival for each transplant or patient, separate analyses were performed for graft and patient survival at three time points. (The analyses were performed using logistic regression, see the *Technical Methods* chapter in the *Executive Summary.*) The analyses also identified donor and recipient characteristics that had a significant impact on survival outcomes. For each *characteristic* (e.g., race, gender) considered in the analyses, a *reference group* was chosen (e.g., White, male) with which the other groups were compared. As a general rule, the largest group or the mean of the characteristic (e.g., mean age for patients who received a single lung transplant was 48 and mean age for patients who received a double lung transplant was 33) is often used as the reference group.

**Table VII-7. National Donor and Recipient Characteristics in Lung Transplants: Percentages by Era and Overall.**

| Characteristics by Category | | ERA 1 1/88-4/92 N=919 | ERA 2 5/92-4/94 N=1216 | OVERALL 1/88-4/94 N=2135 |
|---|---|---|---|---|
| Type of Transplant | Single Left Lung Transplant | 36.0 | 32.3 | 33.9 |
| | Single Right Lung Transplant | 35.1 | 32.2 | 33.4 |
| | Double Lung Transplant | 28.8 | 35.5 | 32.6 |
| Donor Age | 0-5 | 1.6 | 1.5 | 1.5 |
| | 6-10 | 2.4 | 2.6 | 2.5 |
| | 11-17 | 20.2 | 21.6 | 21.0 |
| | 18-35 | 55.2 | 49.1 | 51.7 |
| | 36-49 | 18.0 | 20.1 | 19.2 |
| | 50+ | 2.6 | 5.0 | 4.0 |
| Donor Gender | Female | 28.7 | 30.3 | 29.6 |
| | Male | 71.3 | 69.7 | 70.4 |
| Donor Race | White | 79.1 | 75.8 | 77.2 |
| | Black | 11.3 | 15.7 | 13.8 |
| | Hispanic | 8.6 | 7.2 | 7.8 |
| | Asian | 0.4 | 0.8 | 0.7 |
| | Other | 0.4 | 0.3 | 0.4 |
| | Not Reported | 0.1 | 0.2 | 0.1 |
| Recipient Age | 0-5 | 1.2 | 1.2 | 1.2 |
| | 6-10 | 1.0 | 1.3 | 1.2 |
| | 11-17 | 3.6 | 3.5 | 3.6 |
| | 18-35 | 22.1 | 19.5 | 20.6 |
| | 36-49 | 38.1 | 28.4 | 32.6 |
| | 50+ | 34.1 | 46.1 | 40.9 |
| Recipient Gender | Female | 52.8 | 53.0 | 52.9 |
| | Male | 47.2 | 47.0 | 47.1 |
| Recipient Race | White | 90.2 | 92.0 | 91.2 |
| | Black | 4.1 | 3.9 | 4.0 |
| | Hispanic | 4.0 | 1.7 | 2.7 |
| | Asian | 0.5 | 1.0 | 0.8 |
| | Other | 0.8 | 1.4 | 1.1 |
| | Not Reported | 0.3 | 0.0 | 0.1 |

| | | ERA 1 | ERA 2 | OVERALL |
|---|---|---|---|---|
| **Previous Lung Transplant** | No | 96.0 | 97.0 | 96.6 |
| | Yes | 4.0 | 2.2 | 3.0 |
| | Not Reported | 0.0 | 0.7 | 0.4 |
| **On Ventilator at Transplant** | No | 95.5 | 92.6 | 93.9 |
| | Yes | 3.9 | 3.6 | 3.7 |
| | Not Reported | 0.5 | 3.8 | 2.4 |
| **Medical Condition at Transplant** | In ICU | 7.7 | 5.8 | 6.6 |
| | Hospitalized | 9.5 | 7.6 | 8.4 |
| | Not Hospitalized | 82.4 | 86.2 | 84.5 |
| | Not Reported | 0.4 | 0.4 | 0.4 |
| **Primary Lung Disease at Transplant** | COPD/Emphysema | 26.0 | 38.7 | 33.3 |
| | Fibrosis (Cystic/Idiopathic) | 28.2 | 25.6 | 26.7 |
| | Alpha-1-Antitrypsin Deficiency | 17.2 | 12.1 | 14.3 |
| | Primary Pulmonary Hypertension | 12.5 | 9.5 | 10.8 |
| | Eisenmenger's Syndrome/Congenital | 4.5 | 4.5 | 4.5 |
| | Retransplant | 0.9 | 0.5 | 0.7 |
| | Other | 10.4 | 8.9 | 9.6 |
| | Not Reported | 0.3 | 0.2 | 0.2 |
| **Year of Transplant** | 1988 | 3.6 | 0.0 | 1.5 |
| | 1989 | 10.0 | 0.0 | 4.3 |
| | 1990 | 22.0 | 0.0 | 9.5 |
| | 1991 | 43.6 | 0.0 | 18.8 |
| | 1992 | 20.8 | 28.3 | 25.1 |
| | 1993 | 0.0 | 54.3 | 30.9 |
| | 1994 | 0.0 | 17.4 | 9.9 |
| **Cold Ischemia Time:** | | | | |
| **Single Lung, Left** | Up to 2.5 hrs | 14.5 | 18.3 | 16.6 |
| | > 2.5 to 3 hrs | 16.3 | 13.2 | 14.6 |
| | > 3 - 3.5 hrs | 18.1 | 11.2 | 14.4 |
| | > 3.5 - 4.5 hrs | 25.7 | 32.1 | 29.1 |
| | > 4.5 hrs | 23.0 | 22.9 | 22.9 |
| | Not Reported | 2.4 | 2.3 | 2.3 |

| | | ERA 1 | ERA 2 | OVERALL |
|---|---|---|---|---|
| **Single Lung, Right** | Up to 2.5 hrs | 14.2 | 14.6 | 14.4 |
| | > 2.5 to 3 hrs | 16.1 | 11.0 | 13.3 |
| | > 3 to 3.5 hrs | 18.3 | 14.1 | 16.0 |
| | > 3.5 to 4.5 hrs | 30.0 | 30.9 | 30.5 |
| | > 4.5 hrs | 18.6 | 26.9 | 23.1 |
| | Not Reported | 2.8 | 2.6 | 2.7 |
| **Double Lung, Left** | Up to 3.5 hrs | 18.1 | 17.8 | 17.9 |
| | > 3.5 to 4.5 hrs | 20.4 | 21.1 | 20.8 |
| | > 4.5 to 5.5 hrs | 19.6 | 23.8 | 22.2 |
| | > 5.5 to 6.5 hrs | 18.1 | 18.1 | 18.1 |
| | > 6.5 hrs | 19.2 | 15.5 | 16.9 |
| | Not Reported | 4.5 | 3.7 | 4.0 |
| **Double Lung, Right** | Up to 3.5 hrs | 20.8 | 24.5 | 23.1 |
| | > 3.5 to 4.5 hrs | 24.5 | 23.1 | 23.7 |
| | > 4.5 to 5.5 hrs | 19.6 | 20.4 | 20.1 |
| | > 5.5 to 6.5 hrs | 11.7 | 12.7 | 12.3 |
| | > 6.5 hrs | 13.6 | 14.6 | 14.2 |
| | Not Reported | 9.8 | 4.6 | 6.6 |

The following served as the characteristics and reference groups for ***short term graft and patient*** survival:

- Donor Race -- White, Hispanic, or Asian
- Donor Gender -- male
- Previous Lung Transplant -- none
- Transplant Type -- single lung transplant
- Mean Recipient Age -- 48 years for single lung transplants and 33 years for double lung transplants.
- Recipient Race -- White or Black
- Recipient Gender -- male
- Lung Disease -- COPD/Emphysema (see Table VII-8 for a complete list of disease diagnoses)
- Medical Status -- not hospitalized or in ICU prior to transplant
- Recipient on Ventilator -- no
- Year of Transplant -- 1988 or 1989

The relative impact of each donor and recipient characteristic on short term graft and patient survival outcomes is listed in Table VII-9. For each characteristic, the ***odds ratio*** is the odds of patient death (graft failure) as compared to the reference group, after adjusting for the effects of all other donor and recipient characteristics. An *odds ratio of less than 1* indicates that the characteristic was associated with a *reduced odds* of patient death or graft failure relative to the reference group. An odds ratio of *greater than 1* indicates that the characteristic was associated with an *increased odds* of death relative to the reference group. The corresponding p-value measures how significant the odds ratio is. A p-value less than 0.05 indicates statistical significance and means that there is less than a 5% probability that such difference is due to chance alone. The smaller the p-value, the greater the statistical significance and the less likely the difference is due to chance alone.

**Examples**

In Table VII-9, the odds ratio of graft failure at 1 month post-transplant for a recipient on a ventilator

**Table VII-8. Lung Primary Disease Diagnoses at Time of Transplant**

| |
|---|
| COPD [1] /Emphysema |
| Primary Pulmonary Hypertension |
| Cystic/Idiopathic Fibrosis |
| Alpha-1-Antitrypsin Deficiency (A1A) |
| Congenital |
| - Eisenmenger's syndrome |
| - Other congenital defects |
| Other |
| - Inhalation burns/trauma |
| - Sarcoidosis |
| - Bronchiectasis |
| - Rheumatoid disease |
| - Occupational lung disease |
| - Lymphangioleiomyomatosis |
| - Obliterative bronchiolitis |
| - Pulmonary vascular disease |
| - Other lung disease |

[1] Chronic Obstructive Pulmonary Disease

at the time of transplant was 4.12. This means that, after adjusting for all of the other donor and recipient characteristics, the odds of graft failure within 1 month was 312% greater for recipients on a ventilator than for those not on a ventilator at the time of transplant ((4.12-1)×100%=312%). As another example, the odds ratio of graft failure within 1 month post-transplant for a recipient who had a repeat transplant versus a recipient who received a first transplant was 2.71. After adjusting for the effects of both donor and recipient characteristics, the odds of graft failure within 1 month for a patient who had a repeat transplant was 171% higher ((2.71-1)×100%=171%) than that for a patient who received a first transplant.

The estimated odds ratios for continuous variables (i.e., variables with many possible values) such as cold ischemic time and donor and recipient ages, are less easily interpreted. For these variables, the estimated odds is determined for a set unit increase or decrease from the mean (reference group) of the variable. For example, in Table VII-9, the estimated odds of 1 year graft failure for single lung recipients age 58 compared to the recipient mean age of 48 is 1.28. This means that, after adjusting for the effects of all other characteristics, the odds of graft failure increased by 28% for the first 10 year increase from the mean age.

Mathematically, this 28% was calculated as follows:

$$\text{Odds ratio} = \exp^{[(\frac{58-48}{10})\times 0.18 + (\frac{58-48}{10})^2 \times 0.063]} = 1.28$$

where (58-48) is the amount of increase in years and 10 years is the unit of increase; 0.18 and 0.063 correspond to the coefficients of age per 10 year difference (See Table VII-12 for coefficients). Therefore, the increase in the odds of death or graft failure is (1.28-1)×100%=28%.

**Short Term Graft and Patient Survival**

The characteristics with the strongest impact on short term graft and patient survival were having a previous lung transplant, being on a ventilator at the time of transplant, and having a congenital or pulmonary hypertension diagnosis. The odds of 1 year graft failure was 174% higher if the transplant was a repeat transplant. Double lung transplants had reduced odds of failure or death by 28% at 1 year. If a ventilator was being used at the time of transplant, then the odds of 1 year graft failure was 324% higher than if a ventilator was not being used at the time of transplant. Nearly 99% of the patients that were on a ventilator were also in the intensive care unit (ICU); and 60% of the patients that were in the ICU were on a ventilator. This might explain why being in the ICU did not turn out to be a significant characteristic in the analysis, because most of its impact had already been explained by the use of a ventilator just prior to transplant. Transplants performed after 1989 have a significantly reduced odds of graft failure and patient death. In particular, transplants performed in 1993 and 1994 had a 59% reduced odds of patient death at 1 year post transplant.

## G. LONG TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

In this report, *long term* survival analyses were developed separately from the short term survival analyses. Because this narrative focuses on conditional 3 year survival (survival at 3 years for grafts or patients surviving at least 1 year post-transplant), only conditional 3 year survival data are presented in this text. Both conditional and unconditional 3 year survival rates are provided in the tables for each transplant program presented in

each organ specific volume. The conditional 3 year survival analyses provide an assessment of the donor and recipient characteristics that are independent of those limited to the first year (e.g., surgical complications). Due to the small number of transplants used in the long term analysis (n=608), only a few donor and recipient characteristics were identified (Table VII-10).

The following characteristics and reference groups were used for *long term graft and patient* survival:

- Lung Disease -- non-other group (see Table VII-8 for a complete list of disease diagnoses)
- Mean Cold Ischemic Time -- 224 minutes for single lung transplants and 341 minutes for double lung transplants.
- Mean Recipient Age -- 48 years for single lung recipients and 33 years for double lung recipients.
- Recipient Race -- White, Hispanic, or Asian

Graft and Patient Survival

Recipient age, race, and disease diagnoses remain important predictors of survival outcomes. Black had 132% increased odds of patient death and Other (i.e., non-White, non-Hispanic and non-Asian) races had 83% increased odds of patient odds. Medical condition at transplant, donor characteristics, transplant type (single or double lung), whether recipient had a previous transplant, and recipient gender were no longer significant. It is unclear why older recipients and longer cold ischemic times had lower odds ratios. This could be due to the limited number of transplants in the long term analysis. Or perhaps, these factors were associated with a particular characteristic that had a positive impact on long survival but was not taken into account in the analysis.

## H. STATISTICAL METHODS AND MODELS

***This section provides a brief summary of the statistical methods used to determine survival rates for lung transplants, both nationally and at each transplant program. It is not necessary to read this section in order to utilize the rest of the report. For additional statistical details, please see the Technical Methods chapter in the Executive Summary.***

Model Significance -- $R^2$

The conclusion that there is a "center effect" in lung transplantation often is based on the observation that actual survival rates vary considerably among lung transplant programs. However, in reality, only part of the variability can be attributed to the quality of the program (the so called "center effect"): the rest can be attributed to the differences in donor and recipient characteristics among transplant programs. The degree to which the variability in actual survival rates can be attributed to the specific donor and recipient characteristics in each analysis appears in Table VII-11.

In the table, the values in the column labeled $R^2$ estimate the percentage of variability in the actual survival rates that can be attributed to the covariates in each analysis. *The higher the percentage, the better the analysis explained the individual program outcomes, based on the characteristics examined.* Theoretically, if an analysis contained every covariate that affected survival outcomes, and there were no differences in quality among programs (i.e., no "center effect"), then $R^2$ would equal 100%. In practice, we can never capture every factor that affects outcomes, and it is likely that real differences among programs do exist. This means that any unexplained variation can probably be attributed to a combination of true center effect and covariates not considered in this study. (For details on the $R^2$ calculation, refer to the *Model Significance* section in the *Technical Methods* chapter of the *Executive Summary*.)

The value of $R^2$ estimated from analyses in the 1994 Report was compared to the value of the $R^2$ analyses in the 1997 Report. Note that these analyses are not *directly* comparable since each was used with a different cohort of transplants. The $R^2$ calculations for the 1994 and 1997 reports are similar at the 1 month time point; at 1 year the $R^2$ calculation in the 1997 report is improved by 5%-6% from the 1994 report. Despite the refinements in the 1997 Report, much of the variation in actual survival rates among the 75 transplant programs in the study remains unexplained by the analyses. This suggests that much of the risk involved in transplantation is due to characteristics not described in this report.

**Table VII-9. Impact of Donor and Recipient Characteristics on Short Term Graft and Patient Survival--Lung Transplants**

| Short Term Characteristics | Graft Survival | | | | Patient Survival | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Odds Ratio | P-value | Odds Ratio | P-value | Odds Ratio | P-value | Odds Ratio | P-value |
| Donor Black vs White | 1.303 | 0.168 | 1.329 | 0.046 | 1.256 | 0.259 | 1.356 | 0.037 |
| Donor Hispanic, Asian, Other vs White | 1.435 | 0.103 | 1.426 | 0.037 | 1.386 | 0.158 | 1.458 | 0.030 |
| Donor Female vs Male | 1.345 | 0.051 | 1.268 | 0.037 | 1.270 | 0.134 | 1.187 | 0.144 |
| Previous Lung Transplant: Yes vs No | 2.711 | 0.001 | 2.742 | <0.001 | 3.307 | 0.002 | 3.001 | 0.005 |
| Type of TX: Double vs Single Lung | 0.866 | 0.342 | 0.718 | 0.004 | 0.819 | 0.210 | 0.697 | 0.003 |
| Recipient Age 58 vs 48 for Single Lung, 43 vs 33 for Double Lung [1] | 1.103 | 0.214 | 1.275 | <0.001 | 1.127 | 0.147 | 1.309 | <0.001 |
| Recipient Hispanic, Asian, Other vs White, Black | 1.329 | 0.307 | 1.266 | 0.294 | 1.367 | 0.277 | 1.355 | 0.183 |
| Recipient Male vs Female | 1.474 | 0.008 | 1.304 | 0.013 | 1.447 | 0.015 | 1.247 | 0.044 |
| Pulmonary vs COPD/Emphysema | 4.272 | <0.001 | 2.039 | <0.001 | 4.712 | <0.001 | 2.192 | <0.001 |
| Congenital vs COPD/Emphysema | 5.295 | <0.001 | 2.889 | <0.001 | 5.820 | <0.001 | 2.940 | <0.001 |
| Fibrosis vs COPD/Emphysema | 1.879 | 0.003 | 1.942 | <0.001 | 1.908 | 0.004 | 1.963 | <0.001 |
| A1A vs COPD/Emphysema | 1.790 | 0.013 | 1.564 | 0.006 | 1.903 | 0.008 | 1.582 | 0.006 |
| Other Diagnosis [3] vs COPD/Emphysema | 2.269 | 0.001 | 1.789 | 0.002 | 2.273 | 0.002 | 1.753 | 0.004 |
| In Hospital vs Home or in ICU | 1.137 | 0.584 | 1.503 | 0.018 | 1.161 | 0.541 | 1.426 | 0.046 |
| On Ventilator at Transplant: Yes vs No | 4.118 | <0.001 | 4.243 | <0.001 | 4.226 | <0.001 | 4.898 | <0.001 |
| Transplant Year 1990 vs 1988-1989 | 0.422 | 0.003 | 0.491 | 0.004 | 0.432 | 0.005 | 0.463 | 0.003 |
| Transplant Year 1991 vs 1988-1989 | 0.422 | <0.001 | 0.595 | 0.017 | 0.397 | <0.001 | 0.571 | 0.012 |
| Transplant Year 1992 vs 1988-1989 | 0.288 | <0.001 | 0.560 | 0.006 | 0.290 | <0.001 | 0.564 | 0.008 |
| Transplant Year 1993-1994 vs 1988-1989 | 0.266 | <0.001 | 0.422 | <0.001 | 0.257 | <0.001 | 0.408 | <0.001 |

Notes:

[1] The odds ratio for recipient age does not have a linear relationship. The odds ratio presented in this table is a 10 year increment from the mean age. The mean single and double lung recipient ages were 48 and 33, respectively.

[2] See Table VII-8 for a listing of lung diagnoses.

**Table VII-10. Impact of Donor and Recipient Characteristics on Long-Term Graft and Patient Survival -- Lung Transplants**

| Long Term Characteristics | Graft Survival | | Patient Survival | |
|---|---|---|---|---|
| | Odds Ratio | P-value | Odds Ratio | P-value |
| **Cold Ischemic Time (min) --284 vs 224 for Single Lung and 401 vs 341 for Double Lung [1]** | 0.965 | 0.043 | 0.961 | 0.029 |
| **Recipient Age - 58 vs 48[1]** | 0.834 | 0.026 | 0.871 | 0.098 |
| **Recipient Black vs White** | 2.777 | 0.028 | 2.317 | 0.075 |
| **Recipient Hispanic, Asian, Other vs White** | 1.914 | 0.096 | 1.833 | 0.129 |
| **Other Diagnosis vs Baseline[2]** | 0.527 | 0.057 | 0.593 | 0.119 |

Notes:

[1] The odds ratios for recipient age and cold ischemic time do not have a linear relationship. The odds ratios presented in this table are 10 (age) or 15 (cold ischemic time) unit increases from the mean of each characteristic. The mean single lung recipient age was 48; the mean double lung recipient age was 33. The mean single lung cold ischemic time was 224 minutes; the mean double lung cold ischemic time was 341 minutes.

[2] Baseline includes all the disease groups except "Other" listed in Table VII-8.

**Estimated Coefficients and Standard Errors from the Logistic Regression Models**

Tables VII-12 and VII-13 list the coefficients and the standard errors of the coefficients at each time point for all of the donor and recipient characteristics used in the logistic regression models. Each coefficient is reported on the logistic scale and represents the $\log_e$ odds of graft failure or the $\log_e$ odds of patient mortality for the corresponding characteristic at the specified time after transplant. The adjusted odds ratio on the probability scale may be obtained by applying the exponential function to the coefficient. For further details, see the *Odds Ratios* section in the *Technical Methods* chapter of the *Executive Summary*.

**Expected Lung Transplant Survival Rates**

Table VII-14 shows the 1 year *expected graft* survival rates for lung transplants for a given set of donor and recipient characteristics; Table VII-15 shows the 1 year *expected patient* survival rates. These rates were determined using the following characteristics: recipient age, diagnosis, transplant type, and whether or not the recipient was using a ventilator at the time of transplant. For these analyses, all other characteristics were set to the values for the reference groups, with the exception of the year of transplant (1993-1994). The complete list of reference groups is shown on page 115.

For example, in Table VII-14, the expected 1 year graft survival for a 50 year old male recipient of a first single lung transplant with pulmonary hypertension was 76% if the patient did not require ventilator prior to transplant. In contrast, the expected 1 year graft survival for the same patient was 43% if he was using a ventilator prior to transplant.

## I. SUMMARY

**Study Period**

The 1997 Report was based on 2,135 lung transplants performed in 2,079 patients between January 1, 1988, and April 30, 1994, from 75 transplant programs in the United States. In order to assess changes within transplant programs over time, the data were divided into 2 eras. The first era included transplants performed from January 1, 1988, through April 30, 1992; the second era covered the two year time period from May 1, 1992, through April 30, 1994.

**Table VII-11. Lung Model $R^2$: Comparison of the 1994 and 1997 Reports**

| | Time Point | Report Year | Number of Covariates | $R^2$ |
|---|---|---|---|---|
| **Graft Model $R^2$** | 1 Month | 1997<br>1994 | 20<br>11 | 30<br>30 |
| | 1 Year | 1997<br>1994 | 20<br>11 | 36<br>30 |
| | Cond. 3 Year* | 1997<br>1994 | 5<br>NA | 16<br>NA |
| **Patient Model $R^2$** | 1 Month | 1997<br>1994 | 20<br>11 | 32<br>34 |
| | 1 Year | 1997<br>1994 | 20<br>11 | 37<br>32 |
| | Cond. 3 Year* | 1997<br>1994 | 5<br>NA | 18<br>NA |

* Conditional 3 year analysis was not performed in the 1994 Report.

**Table VII-12. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Short Term Lung Transplant Survival**

| Short Term Characteristics | Graft Survival | | | | Patient Survival | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| **Intercept** | -1.9361 | 0.276 | -1.0654 | 0.224 | -1.9652 | 0.288 | -1.0617 | 0.230 |
| **Donor Black vs White** | 0.2644 | 0.192 | 0.2845 | 0.143 | 0.2276 | 0.201 | 0.3048 | 0.146 |
| **Donor Hispanic, Asian, Other vs White** | 0.3615 | 0.222 | 0.3552 | 0.171 | 0.3261 | 0.231 | 0.3772 | 0.174 |
| **Donor Female vs Male** | 0.2963 | 0.152 | 0.2371 | 0.113 | 0.2391 | 0.159 | 0.1710 | 0.117 |
| **Previous Lung Transplant: Yes vs No** | 0.9975 | 0.310 | 1.0086 | 0.296 | 1.1961 | 0.394 | 1.0990 | 0.389 |
| **Type of TX: Double vs Single Lung** | -0.1442 | 0.152 | -0.3317 | 0.116 | -0.1993 | 0.159 | -0.3605 | 0.120 |
| **Recipient Age-Linear (per 10 years) [1]** | 0.1059 | 0.067 | 0.1801 | 0.050 | 0.1207 | 0.070 | 0.2065 | 0.051 |
| **Recipient Age-Quadratic (per 10 years)[1,2]** | -0.0076 | 0.029 | 0.0626 | 0.023 | -0.0015 | 0.031 | 0.0632 | 0.023 |
| **Recipient Hispanic, Asian and Other vs White, Black** | 0.2841 | 0.278 | 0.2356 | 0.225 | 0.3129 | 0.288 | 0.3039 | 0.228 |
| **Recipient Male vs Female** | 0.3880 | 0.146 | 0.2654 | 0.107 | 0.3692 | 0.152 | 0.2209 | 0.110 |

| Short Term Characteristics | Graft Survival | | | | Patient Survival | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| **Pulmonary vs COPD/Emphysema** | 1.4520 | 0.241 | 0.7126 | 0.189 | 1.5502 | 0.250 | 0.7850 | 0.193 |
| **Congenital vs COPD/Emphysema** | 1.6668 | 0.302 | 1.0609 | 0.251 | 1.7614 | 0.310 | 1.0786 | 0.256 |
| **Fibrosis vs COPD/Emphysema** | 0.6305 | 0.216 | 0.6637 | 0.152 | 0.6459 | 0.227 | 0.6743 | 0.156 |
| **A1A vs COPD/Emphysema** | 0.5821 | 0.233 | 0.4472 | 0.164 | 0.6434 | 0.243 | 0.4558 | 0.168 |
| **Other Diagnoses [3] vs COPD/Emphysema** | 0.8193 | 0.258 | 0.5814 | 0.187 | 0.8213 | 0.272 | 0.5612 | 0.193 |
| **In Hospital vs Home or in ICU** | 0.1286 | 0.235 | 0.4072 | 0.172 | 0.1497 | 0.245 | 0.3550 | 0.178 |
| **On Ventilator at Transplant: Yes vs No** | 1.4154 | 0.280 | 1.4452 | 0.269 | 1.4412 | 0.301 | 1.5888 | 0.290 |
| **Transplant Year 1990 vs 1988-1989** | -0.8620 | 0.287 | -0.7108 | 0.247 | -0.8395 | 0.297 | -0.7703 | 0.256 |
| **Transplant Year 1991 vs 1988-1989** | -0.8638 | 0.251 | -0.5190 | 0.217 | -0.9248 | 0.262 | -0.5605 | 0.224 |
| **Transplant Year 1992 vs 1988-1989** | -1.2433 | 0.251 | -0.5805 | 0.211 | -1.2383 | 0.259 | -0.5720 | 0.216 |
| **Transplant Year 1993-1994 vs 1988-1989** | -1.3235 | 0.239 | -0.8630 | 0.205 | -1.3577 | 0.248 | -0.8960 | 0.210 |

Notes:

[1] In the analysis, the continuous covariates recipient age, was centered about its mean. The mean single and double lung recipient ages were 48 and 33, respectively.

[2] Modeling the continuous covariate, recipient age, with a linear and quadratic term (the square of the linear term) is necessary due to the relationship between the covariate and the odds of graft failure or patient death.

[3] See Table VII-8 for a listing of Other lung diagnosis.

**Table VII-13. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Long Term Lung Transplant Survival**

| Long Term Characteristics | Graft Survival | | Patient Survival | |
|---|---|---|---|---|
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| **Intercept** | -1.1550 | 0.170 | -1.2077 | 0.109 |
| **Cold Ischemia Time (per 15 minutes) [1]** | -0.0359 | 0.018 | -0.0395 | 0.018 |
| **Recipient Age (per 10 years) [1]** | -0.1814 | 0.081 | -0.1381 | 0.083 |
| **Recipient Black vs White, Hispanic, Asian** | 1.0215 | 0.466 | 0.8403 | 0.471 |
| **Recipient Other vs White, Hispanic, Asian** | 0.6493 | 0.390 | 0.6061 | 0.399 |
| **Other Diagnosis vs Baseline [2]** | -0.6399 | 0.336 | -0.5223 | 0.335 |

Notes:

[1] In the analysis, the continuous covariates, recipient age and cold ischemic time, were centered about their mean. The mean single and double lung recipient ages were 48 and 33, respectively. The mean single lung cold ischemic time was 224 minutes; the mean double lung cold ischemic time was 341 minutes.

[2] Baseline includes all the disease groups except "Other" in Table VII-8.

**Table VII-14. Expected U.S. 1 Year Graft Survival Rates -- Lung Transplants Stratified by Recipient Age, Diagnosis, Transplant Type and Ventilator Status**

| Age | Diagnosis | Single Lung Transplant | | Double Lung Transplant | |
|---|---|---|---|---|---|
| | | No Ventilator | Ventilator | No Ventilator | Ventilator |
| 5 | COPD/Emphysema* | NA | NA | NA | NA |
| | Fibrosis (Cystic/Idiopathic) | 70.7 | 36.3 | 83.3 | 54.1 |
| | Alpha-1-Antitrypsin* | NA | NA | NA | NA |
| | Pulmonary Hypertension | 69.7 | 35.2 | 82.6 | 52.9 |
| | Congenital | 61.9 | 27.7 | 77.1 | 44.2 |
| | Other | 72.4 | 38.2 | 84.5 | 56.1 |
| 20 | COPD/Emphysema | 87.5 | 62.2 | 91.6 | 72.0 |
| | Fibrosis (Cystic/Idiopathic) | 78.2 | 45.8 | 84.9 | 56.9 |
| | Alpha-1-Antitrypsin | 81.7 | 51.2 | 87.4 | 62.2 |
| | Pulmonary Hypertension | 77.4 | 44.6 | 84.2 | 55.7 |
| | Congenital | 70.7 | 36.3 | 79.0 | 47.1 |
| | Other | 79.6 | 47.9 | 85.9 | 58.9 |
| 35 | COPD/Emphysema | 88.7 | 64.8 | 90.2 | 68.5 |
| | Fibrosis (Cystic/Idiopathic) | 80.1 | 48.7 | 82.6 | 52.8 |
| | Alpha-1-Antitrypsin | 83.3 | 54.1 | 85.5 | 58.2 |
| | Pulmonary Hypertension | 79.3 | 47.5 | 81.9 | 51.6 |
| | Congenital | 73.0 | 39.0 | 76.1 | 42.9 |
| | Other | 81.4 | 50.8 | 83.8 | 54.9 |
| 50 | COPD/Emphysema | 86.9 | 60.9 | 85.5 | 58.1 |
| | Fibrosis (Cystic/Idiopathic) | 77.3 | 44.5 | 75.2 | 41.7 |
| | Alpha-1-Antitrypsin | 80.9 | 49.9 | 79.0 | 47.0 |
| | Pulmonary Hypertension | 76.4 | 43.3 | 74.3 | 40.5 |
| | Congenital* | NA | NA | NA | NA |
| | Other | 78.7 | 46.6 | 76.7 | 43.7 |
| 65 | COPD/Emphysema | 80.9 | 49.9 | 73.9 | 40.1 |
| | Fibrosis (Cystic/Idiopathic) | 68.5 | 33.9 | 59.4 | 25.6 |
| | Alpha-1-Antitrypsin | 73.0 | 38.9 | 64.5 | 30.0 |
| | Pulmonary Hypertension | 67.5 | 32.8 | 58.2 | 24.7 |
| | Congenital* | NA | NA | NA | NA |
| | Other | 70.3 | 35.8 | 61.3 | 27.2 |

* - Disease not applicable to age group.

**Table VII-15. Expected U.S. 1 Year Patient Survival Rates -- Lung Transplants Stratified by Recipient Age, Diagnosis, Transplant Type and Ventilator Status**

| Age | Diagnosis | Single Lung Transplant | | Double Lung Transplant | |
|---|---|---|---|---|---|
| | | No Ventilator | Ventilator | No Ventilator | Ventilator |
| 5 | COPD/Emphysema* | NA | NA | NA | NA |
| | Fibrosis (Cystic/Idiopathic) | 70.7 | 36.3 | 83.3 | 54.1 |
| | Alpha-1-Antitrypsin* | NA | NA | NA | NA |
| | Pulmonary Hypertension | 69.7 | 35.2 | 82.6 | 52.9 |
| | Congenital | 61.9 | 27.7 | 77.1 | 44.2 |
| | Other | 72.4 | 38.2 | 84.5 | 56.1 |
| 20 | COPD/Emphysema | 87.5 | 62.2 | 91.6 | 72.0 |
| | Fibrosis (Cystic/Idiopathic) | 78.2 | 45.8 | 84.9 | 56.9 |
| | Alpha-1-Antitrypsin | 81.7 | 51.2 | 87.4 | 62.2 |
| | Pulmonary Hypertension | 77.4 | 44.6 | 84.2 | 55.7 |
| | Congenital | 70.7 | 36.3 | 79.0 | 47.1 |
| | Other | 79.6 | 47.9 | 85.9 | 58.9 |
| 35 | COPD/Emphysema | 88.7 | 64.8 | 90.2 | 68.5 |
| | Fibrosis (Cystic/Idiopathic) | 80.1 | 48.7 | 82.6 | 52.8 |
| | Alpha-1-Antitrypsin | 83.3 | 54.7 | 85.5 | 58.2 |
| | Pulmonary Hypertension | 79.3 | 47.5 | 81.9 | 51.6 |
| | Congenital | 73.0 | 39.0 | 76.1 | 42.9 |
| | Other | 81.4 | 50.8 | 83.8 | 54.9 |
| 50 | COPD/Emphysema | 86.9 | 60.9 | 85.5 | 58.1 |
| | Fibrosis (Cystic/Idiopathic) | 77.3 | 44.5 | 75.2 | 41.7 |
| | Alpha-1-Antitrypsin | 80.9 | 49.9 | 79.0 | 47.0 |
| | Pulmonary Hypertension | 76.4 | 43.3 | 74.3 | 40.5 |
| | Congenital* | NA | NA | NA | NA |
| | Other | 78.7 | 46.6 | 76.7 | 43.7 |
| 65 | COPD/Emphysema | 80.9 | 49.9 | 73.9 | 40.1 |
| | Fibrosis (Cystic/Idiopathic) | 68.5 | 33.9 | 59.4 | 25.6 |
| | Alpha-1-Antitrypsin | 73.0 | 38.9 | 64.5 | 30.0 |
| | Pulmonary Hypertension | 67.5 | 32.8 | 58.2 | 24.7 |
| | Congenital* | NA | NA | NA | NA |
| | Other | 70.3 | 35.8 | 61.3 | 27.2 |

* - Disease not applicable to age group.

Table VI-16. Comparison of 1 Month and 1 Year Actual Survival Rates Between Eras

| | 1 Month | | 1 Year | |
|---|---|---|---|---|
| | Era 1 | Era 2 | Era 1 | Era 2 |
| Graft Survival (%) | 83.5% | 89.3% | 66.6% | 73.4% |
| Average No. of Transplants/Month | 18 | 51 | 18 | 51 |
| Patient Survival (%) | 84.5% | 90.0% | 68.4% | 74.5% |
| Average No. of Patients/Month | 17 | 50 | 17 | 50 |

## Survival Rates

Survival rates were computed at 1 month, 1 year, and 3 years, both nationally and for each transplant program. Three year survival was determined in two ways: (1) conditional 3 year survival (i.e., survival at 3 years for those who survived at least 1 year post-transplant), and (2) unconditional 3 year survival. The emphasis on long term survival in this chapter is on the conditional 3-year survival rates because the conditional 3-year analysis provides an assessment of characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

The national graft and patient survival rates and completeness of follow-up at 1 month, 1 year, and conditional 3 years are shown in Tables VII-1 and VII-2. The percent of programs with graft and patient follow-up data at 1 year was more than 98%; at conditional 3 years the percent of programs with follow-up data was 95%.

There was a marked increase in the number of lung transplants from Era 1 to Era 2. As demonstrated in Table VII-16, the number of lung transplants nearly tripled, from an average of 18 transplants per month in Era 1 to an average of 51 per month in Era 2.

For the majority of transplant programs, the difference between actual and expected survival rates was not statistically significant (See Figures VII-1 and VII-3). In general, large differences (either higher or lower) were nearly always found among programs that reported relatively few transplants (see Figure VII-2). Therefore, when evaluating survival rates for a program, it is also important to consider the number of transplants performed there.

## Differences Between Short Term and Long Term Characteristics

The 1997 Report includes an extensive list of characteristics that have a significant impact on both short and long term graft and patient survival.

Characteristics with the strongest impact on *short term survival* were:

- Recipient received a previous lung transplant
- Transplant type was double or single lung transplant
- Disease diagnosis
- Recipient on a ventilator at transplant
- Transplant year

Characteristics with the strongest impact on *long term survival* was:

- Recipient race
- Recipient age
- Disease diagnosis

## J. FINAL WORDS

The purpose of this report is to provide updated information on survival outcomes both nationally and at specific transplant programs, and to enhance the awareness of program performance in the U.S. However, the assessment of a transplant program should not be based solely on the survival rates provided in this report. Some of the other important factors to consider are the experience of the transplant team, support personnel, the cost of the procedure, and the quality and location of post-transplant services.

# VIII. HEART-LUNG CHAPTER

# VIII. HEART-LUNG TRANSPLANT SURVIVAL RATES

*For a Summary of this chapter, see page 139. For definitions of any terms used here, please refer to the User's Guide in the Heart-Lung volume.*

## A. INTRODUCTION

This report of heart-lung transplant survival rates is based upon verified Scientific Registry data for 373 transplants involving 370 patients from 58 heart-lung transplant programs in the United States. Each program reporting at least one heart-lung transplant between January 1, 1988, and April 30, 1994, was included. Multi-organ transplants were excluded.

Short term survival is defined as survival at 1 month and 1 year post-transplant. Short term survival rates are based on all transplants in the study for which there are follow-up data.

Long term survival is defined in two ways:

- unconditional survival at 3 years post-transplant, and
- survival at 3 years post-transplant for those who survived at least 1 year, referred to as **conditional 3 year survival**.

The long term survival rates are based on all transplants between January 1, 1988, and April 30, 1992, for which there are follow-up data. This cohort was chosen to ensure that the maximum number of transplants with follow-up data was used to determine long term survival rates. Please note that this report emphasizes *conditional* 3-year survival rates. This is because the conditional 3-year analysis assesses factors independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

## B. COMPLETENESS OF FOLLOW-UP DATA AND OVERALL GRAFT AND PATIENT SURVIVAL RATES

For graft survival, completeness of follow-up data and overall actual survival rates at each time point are shown in Table VIII-1; patient survival data are shown in Table VIII-2.

Patient (graft) follow-up data were considered complete when:

- the patient was alive (heart and lung were functioning) and the duration of survival (function) was equal to or exceeded the specified time after transplant (i.e., 1 month, 1 or 3 years), or
- the patient died (both heart and lung failed) and a valid date of death (failure) was reported.

The percentages of complete follow-up data ranged from a low of 96.7% for the conditional 3 year time point to a high of 99.6% for the 1 month time point. Patient survival rates are similar to graft survival rates since patient death follows graft failure unless the patient is retransplanted.

Overall survival rates also are presented in the tables. If a graft had incomplete follow-up data, the observation was weighted to account for the time during which the graft was known to be functioning. Therefore, the actual graft survival rate reflects the weighted proportion of grafts functioning at the specified time interval. Patient survival rates were computed in a similar way (see the *Technical Methods* chapter of the *Executive Summary*).

In the cohort of transplants (1/1/88 - 4/30/92) used to compute conditional 3 year survival rates, patients (grafts) who did not survive to 1 year after transplant were excluded from the analyses. Therefore, the total number of patients (grafts) for the conditional 3 year analysis was less than that for the 1 month and 1 year analyses.

Please note that the conditional 3 year graft and patient survival rates in Tables VIII-1 and VIII-2 may be higher than the 1 year graft survival rates. This is possible because the conditional 3 year survival rate is the 3 year survival rate for patients (grafts) who (which) survived at least 1 year post-transplant.

For example: Program A performed a total of five transplants between 1/1/88 and 4/30/92. Two of the heart-lungs failed prior to 1 year post-transplant and

the remaining three heart-lungs survived to 3 years after transplant. In this example, Program A has a 1 year graft survival rate of 60% (3 out of 5 heart-lungs were functioning at 1 year post-transplant). However, the conditional 3 year survival rate for Program A is 100% because all three heart-lungs that were functioning at 1 year after transplant also were functioning at 3 years post-transplant. The same calculations are used for patient survival. See the *Technical Methods* chapter of the *Executive Summary* for more specific definitions of follow-up data and the calculations for actual graft and patient survival.

Overall Graft and Patient Survival Rates by Era

In this report, short term survival also is reported by era. Separate eras were used to determine whether there were any improvements over time in the short term survival rates. Era 1 is defined as all transplants occurring between January 1, 1988, and April 30, 1992; Era 2 includes all transplants occurring between May 1, 1992, and April 30, 1994.

The overall graft and patient survival rates by era are presented in the last two columns of Table VIII-1 and Table VIII-2, respectively. The results demonstrate an increase in 1 year graft and patient survival rates over time.

## C. GRAFT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

For each transplant program, actual and expected survival rates were calculated at 1 month, 1 year, and 3 years conditional on survival at 1 year. Survival rates at each time point were determined using a specific cohort of transplants (shown in Tables VIII-1 and VIII-2). Expected survival rates were determined for each transplant program based on its specific patient and donor characteristics. These expected outcomes were statistically adjusted for many important prognostic variables, or covariates, that were used in the survival analysis. In other words, they take into account many different characteristics that affect survival. For example: if Program A transplanted many more "high risk" recipients than Program B, then Program A would have a lower *expected* survival rate than Program B.

**Table VIII-1. Completeness of Graft Follow-Up Data and Actual Survival Rates for Heart-Lung Transplants**

| Time | Cohort | Number of Transplants | Percent with Follow-Up Data | Graft Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 1 Month | 1/1/88 - 4/30/94 | 373 | 99.5 | 81.9 | 82.2 | 81.3 |
| 1 Year | 1/1/88 - 4/30/94 | 373 | 98.1 | 61.9 | 58.5 | 70.5 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 153 | 96.7 | 80.1* | 80.1* | N/A* |

**Table VIII-2. Completeness of Patient Follow-Up Data and Actual Survival Rates for Heart-Lung Transplants**

| Time | Cohort | Number of Patients | Percent with Follow-Up Data | Patient Survival (%) | | |
|---|---|---|---|---|---|---|
| | | | | Overall | Era 1 | Era 2 |
| 1 Month | 1/1/88 - 4/30/94 | 370 | 99.2 | 82.2 | 82.5 | 81.3 |
| 1 Year | 1/1/88 - 4/30/94 | 370 | 98.1 | 61.9 | 58.7 | 69.7 |
| Cond. 3 Years | 1/1/88 - 4/30/92 | 151 | 96.7 | 81.2* | 81.2* | N/A* |

* The cohort used to determine the overall conditional 3 year survival rate is the same as the Era 1 cohort. Therefore, the overall conditional 3 year survival rates are identical to the conditional 3 year survival rates for Era 1. There is no conditional 3 year survival rate calculated for Era 2 due to insufficient follow-up data on patients who received transplants in Era 2.

If a program's *actual* survival rate was *greater* than its expected survival rate, this means that the program's actual results were higher than the national results for transplants *with the same donor and recipient characteristics*. If a program's *actual* survival rate was *less than* its expected survival rate, this means that the program's actual results were lower than the national results for transplants *with the same donor and recipient characteristics*. The difference between the actual and expected rate may have occurred by chance and, therefore, may not be statistically significant. Furthermore, even a statistically significant difference, one that most likely did not occur by chance, may not be clinically significant (i.e., medically important). A formal description of the methods used to determine actual and expected survival rates appears in the *Technical Methods* chapter of the *Executive Summary*.

Table VIII-3 shows the percentages of heart-lung transplant programs by category of graft survival rates, both for actual and expected survival. The 1 year survival rates showed a greater variation among programs than the 1 month and conditional 3 year survival rates. At 1 month, 47% of programs had actual survival rates greater than 90%. At 1 year, this fell to 26%. However, this percentage increased to 48% for the conditional 3 year survival rates. The distribution of the expected survival rates shows a similar trend. The results indicate that there are more programs with high survival rates (>90%) at the conditional 3 year time point than there are at the 1 year time point. *This is because the most critical period of time for graft survival is the first year post-transplant.* Those who survive the first year are very likely to survive 3 years post-transplant.

The percentages of programs by short term graft survival rates and eras, both for actual and expected survival, are summarized in Table VIII-4. The results demonstrate a substantial improvement in graft survival over time because a greater percentage of programs had actual survival rates higher than 90% in Era 2.

## Differences in Actual and Expected Survival Rates

For most programs, the difference between the actual survival rate and the expected survival rate was not statistically significant. Figure VIII-1 shows the percentages of programs whose actual graft survival rates were either above, not significantly different from, or below expected graft survival rates at three time points. Actual survival rates shown in the figure to be either greater than or less than expected survival rates were statistically significant. Overall, there were more programs that fell significantly below expected results than programs that were significantly above expected results. However, for the majority of the transplant programs, the difference in actual and expected graft survival was not statistically significant and varied little across time points.

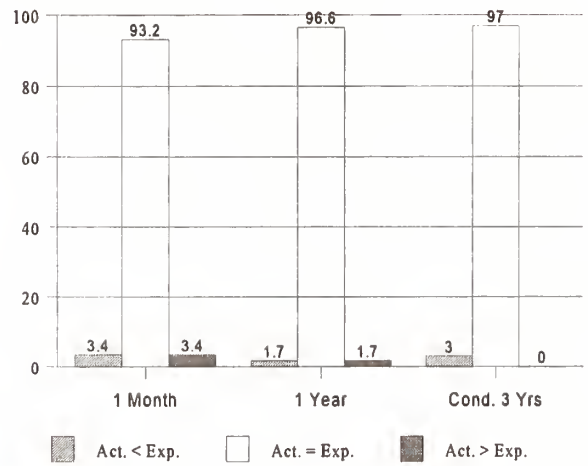
**Table VIII-3. Percentages of Heart-Lung Transplant Programs by Graft Survival Rates**

| Graft Survival Rates (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 1 Month (n= 58) | 1 Year (n=58) | Cond. 3 Yrs (n=33) | 1 Month (n=58) | 1 Year (n=58) | Cond. 3 Yrs (n=33) |
| 0-60 | 22.4 | 50.0 | 18.2 | 5.2 | 32.8 | 9.1 |
| >60-70 | 13.8 | 10.3 | 18.2 | 5.2 | 48.3 | 9.1 |
| >70-80 | 13.8 | 10.3 | 9.1 | 12.1 | 19.0 | 27.3 |
| >80-90 | 3.4 | 3.4 | 6.1 | 72.4 | 0.0 | 39.4 |
| >90-100 | 46.6 | 25.9 | 48.5 | 5.2 | 0.0 | 15.2 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

**Table VIII-4. Percentages of Heart-Lung Transplant Programs by Graft Survival Rates and Era**

| Graft Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Era 1 (n=46) | Era 2 (n=33) | Era 1 (n=46) | Era 2 (n=33) | Era 1 (n=46) | Era 2 (n=33) | Era 1 (n=46) | Era 2 (n=150) |
| 0-60 | 30.4 | 15.2 | 63.0 | 36.4 | 8.7 | 0.0 | 43.5 | 15.2 |
| >60-70 | 6.5 | 12.1 | 4.3 | 3.0 | 4.3 | 6.1 | 43.5 | 45.5 |
| >70-80 | 15.2 | 3.0 | 10.9 | 3.0 | 10.9 | 9.1 | 10.9 | 39.4 |
| >80-90 | 4.3 | 3.0 | 4.3 | 6.1 | 76.1 | 72.7 | 2.2 | 0.0 |
| >90-100 | 43.5 | 66.7 | 17.4 | 51.5 | 0.0 | 12.1 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

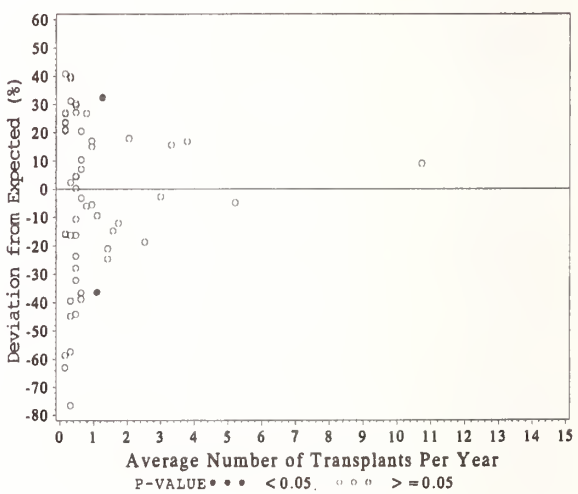
**Figure VIII-1. Percentages of Heart-Lung Transplant Programs with Actual Graft Survival Rates Above, Below, or Equal to Expected Survival Rates. ***




*Actual survival rates above or below expected survival rates are statistically significant and varied little across time points.

At all time points, the larger differences in actual and expected rates were nearly always seen in programs that reported relatively few transplants during the period. This occurs because programs that do not perform many transplants tend to have highly variable outcomes. To illustrate this, Figure VIII-2 shows a scatter plot of the average number of transplants per year (transplant volume) versus the difference in 1 year actual and expected graft survival. Nearly all differences greater than 10% (either positive or negative) are found among transplant programs that perform very few transplants per year.

**Figure VIII-2. Heart-Lung Transplant Volume vs Difference in Actual and Expected 1 Year Graft Survival Rates.**




*Please note that actual survival rates which differ from expected survival rates are not always statistically significant and even statistically significant differences may not be clinically significant.*

## D. PATIENT SURVIVAL -- PERCENTAGES OF ACTUAL AND EXPECTED SURVIVAL RATES

The percentages of programs by patient survival rates for both actual and expected survival are shown in Table VIII-5; the percentages of programs by survival rates and eras are shown in Table VIII-6. Note that both actual and expected patient survival rates were higher and less variable at each time point than were actual and expected graft survival rates. As with graft survival, the outcomes in Era 2 were better than in Era 1.

Table VIII-5. Percentages of Heart-Lung Transplant Programs by Patient Survival Rates

| Patient Survival Rates (%) | Actual | | | Expected | | |
|---|---|---|---|---|---|---|
| | 1 Month (n=58) | 1 Year (n=58) | Cond. 3 Yrs (n=33) | 1 Month (n=58) | 1 Year (n=58) | Cond. 3 Yrs. (n=33) |
| 0-70 | 36.2 | 60.3 | 36.4 | 10.3 | 79.3 | 21.2 |
| >70-80 | 13.8 | 10.3 | 6.1 | 12.1 | 20.7 | 21.2 |
| >80-90 | 3.4 | 3.4 | 9.1 | 72.4 | 0.0 | 42.4 |
| >90-95 | 1.7 | 0.0 | 3.0 | 5.2 | 0.0 | 6.1 |
| >95-100 | 44.8 | 25.9 | 45.5 | 0.0 | 0.0 | 9.1 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

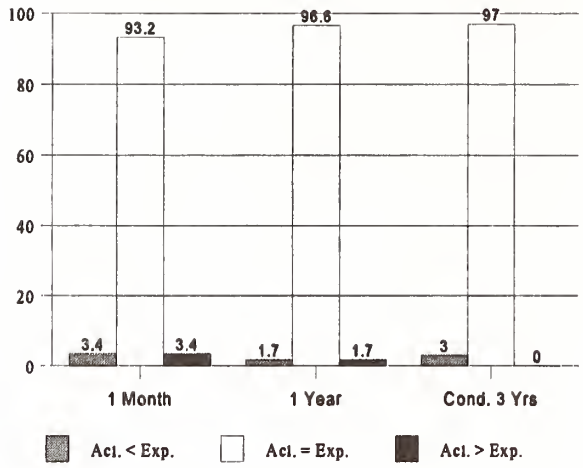
Table VIII-6. Percentages of Heart-Lung Transplant Programs by Patient Survival Rates and Era

| Patient Survival Rates (%) | Actual | | | | Expected | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Era 1 (n=46) | Era 2 (n=33) | Era 1 (n=46) | Era 2 (n=33) | Era 1 (n=46) | Era 2 (n=33) | Era 1 (n=46) | Era 2 (n=33) |
| 0-70 | 37.0 | 27.3 | 67.4 | 39.4 | 13.0 | 3.0 | 84.8 | 60.6 |
| >70-80 | 15.2 | 3.0 | 10.9 | 3.0 | 10.9 | 12.1 | 15.2 | 39.4 |
| >80-90 | 4.3 | 3.0 | 4.3 | 6.1 | 76.1 | 72.7 | 0.0 | 0.0 |
| >90-95 | 2.2 | 3.0 | 0.0 | 0.0 | 0.0 | 12.1 | 0.0 | 0.0 |
| >95-100 | 41.3 | 63.6 | 17.4 | 51.5 | 0.0 | 0.0 | 0.0 | 0.0 |
| TOTAL | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

### Differences in Actual and Expected Survival Rates

The percentage of programs with actual patient survival rates significantly above their expected rates was greater at 1 month and conditional 3 years than at 1 year (see Figure VIII-3). Overall, there were more programs that fell significantly below expected results than above expected results. However, for the majority of transplant programs, the difference in actual and expected patient survival was not statistically significant and varied little across time points.

**Figure VIII-3. Percentages of Heart-Lung Transplant Programs with Actual Patient Survival Rates Above, Below, or Equal to Expected Survival Rates. ***




*Actual survival rates above or below expected survival rates are statistically significant and varied little across time points.

## E. NATIONAL DISTRIBUTION OF DONOR AND RECIPIENT CHARACTERISTICS

The national distribution of donor and recipient characteristics for heart-lung transplants, presented in percentages, is shown in Table VIII-7. Each of these donor and recipient characteristics was included in the analyses for graft or patient survival, and used to determine an expected survival rate for each transplant. The majority of heart-lungs transplanted were recovered from white male donors between the ages of 18 and 35. Sixty percent of the donor heart-lungs had cold ischemic times less than 3.5 hours. The majority of heart-lung recipients were white females between the ages of 18-35. Most recipients (74%) were not hospitalized prior to transplant. The main indication for transplant was a congenital diagnosis or Eisenmenger's syndrome (32%). Of the 373 heart-lung transplants performed, only 2% were due to repeat transplants.

### Donor and Recipient Trends

National donor and recipient characteristics differed between Era 1 and Era 2. The percentage of donors less 18 years increased to 50% in Era 2 compared to 37% in Era 1. Minority donation increased in Era 2 compared to Era 1. In Era 2 the percentage of recipients less than 18 years increased to 26% compared to only 14% in Era 1. The percentage of minority recipients also increased during the second era. A congenital diagnosis, including Eisenmenger's syndrome, was the main indication (51%) for transplant in Era 2. Mean cold ischemic time increased during the second era also.

## F. SHORT TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

To determine the expected survival for each transplant or patient, separate analyses were performed for graft and patient survival at three time points. (The analyses were performed using logistic regression, for a description, see the *Technical Methods* chapter in the *Executive Summary.*) The analyses also identified donor and recipient characteristics that had a significant impact on survival outcomes. For each *characteristic* (e.g., race, gender) considered in the analyses, a *reference group* was chosen (e.g., White, male) with which the other groups were compared. As a general rule, the largest group or the mean of the characteristic (e.g., mean recipient age=45) is often used as the reference group.

The following served as the characteristics and reference groups for ***short term graft and patient*** survival:

- Mean Donor Age -- 22 years
- Mean Cold Ischemic Time -- 163 minutes
- Previous Heart-Lung Transplant -- none
- Mean Recipient Age -- 45 years
- Recipient Gender -- female
- Indication for Transplant -- congenital, including Eisenmenger's syndrome (see Table VIII-8 for a complete list of diagnoses)
- On Ventilator at Transplant -- no
- Year of Transplant -- 1988-1992

The relative impact of each donor and recipient characteristic on short term graft and patient survival outcomes is listed in Table VIII-9. For each characteristic, the ***odds ratio*** is the odds of patient death (graft failure) as compared to the reference group, after adjusting for the effects of all other donor and recipient characteristics. An *odds ratio of*

**Table VIII-7. National Donor and Recipient Characteristics in Heart-Lung Transplants: Percentages by Era and Overall**

| Characteristics | | ERA 1 1/88-4/92 N=265 | ERA 2 5/92-4/94 N=108 | OVERALL 1/88-4/94 N=373 |
|---|---|---|---|---|
| **Donor Age (years)** | 0-5 | 6.0 | 13.9 | 8.3 |
| | 6-10 | 3.8 | 6.5 | 4.6 |
| | 11-17 | 26.8 | 29.6 | 27.6 |
| | 18-35 | 45.3 | 27.8 | 40.2 |
| | 36-49 | 17.0 | 18.5 | 17.4 |
| | 50+ | 1.1 | 3.7 | 1.9 |
| **Donor Gender** | Female | 42.3 | 41.7 | 42.1 |
| | Male | 57.7 | 58.3 | 57.9 |
| **Donor Race** | White | 81.1 | 74.1 | 79.1 |
| | Black | 9.1 | 11.1 | 9.7 |
| | Hispanic | 7.5 | 13.9 | 9.4 |
| | Asian | 1.9 | 0.9 | 1.6 |
| | Other | 0.4 | 0.0 | 0.3 |
| **Recipient Age (years)** | 0-5 | 4.2 | 12.0 | 6.4 |
| | 6-10 | 3.4 | 1.9 | 2.9 |
| | 11-17 | 6.8 | 12.0 | 8.3 |
| | 18-35 | 46.0 | 41.7 | 44.8 |
| | 36-49 | 32.5 | 22.2 | 29.5 |
| | 50+ | 7.2 | 10.2 | 8.0 |
| **Recipient Gender** | Female | 55.1 | 56.5 | 55.5 |
| | Male | 44.9 | 43.5 | 44.5 |
| **Recipient Race** | White | 92.1 | 84.3 | 89.8 |
| | Black | 2.6 | 6.5 | 3.8 |
| | Hispanic | 3.0 | 4.6 | 3.5 |
| | Asian | 0.4 | 1.9 | 0.8 |
| | Other | 1.9 | 1.9 | 1.9 |
| | Not Reported | 0.0 | 0.9 | 0.3 |
| **Previous Heart-lung Transplant** | No | 97.7 | 93.5 | 96.5 |
| | Yes | 2.3 | 1.9 | 2.1 |
| | Not Reported | 0.0 | 4.6 | 1.3 |

| | | ERA 1 | ERA 2 | OVERALL |
|---|---|---|---|---|
| **On Ventilator at Transplant** | No | 94.0 | 83.3 | 90.9 |
| | Yes | 4.2 | 8.3 | 5.4 |
| | Not Reported | 1.9 | 8.3 | 3.8 |
| **Medical Condition at Transplant** | In ICU | 14.0 | 17.6 | 15.0 |
| | Hospitalized | 11.3 | 6.5 | 9.9 |
| | Not Hospitalized | 74.7 | 73.1 | 74.3 |
| | Not Reported | 0.0 | 2.8 | 0.8 |
| **Diagnosis at Transplant** | Congenital/Eisenmenger | 32.1 | 51.9 | 37.8 |
| | Primary Pulmonary Hypertension | 34.0 | 24.1 | 31.1 |
| | Cystic Fibrosis | 13.2 | 1.9 | 9.9 |
| | Alpha-1-Antitrypsin Deficiency | 6.4 | 1.9 | 5.1 |
| | COPD/Emphysema | 2.6 | 3.7 | 2.9 |
| | Retransplant | 2.3 | 1.9 | 2.1 |
| | Other | 9.4 | 8.3 | 9.1 |
| | Not Reported | 0.0 | 6.5 | 1.9 |
| **Cold Ischemia Time** | Up to 1.5 hrs | 12.1 | 0.9 | 8.8 |
| | > 1.5 - 2.5 hrs | 23.8 | 15.7 | 21.4 |
| | > 2.5 - 3.5 hrs | 32.1 | 25.9 | 30.3 |
| | > 3.5 - 4.5 hrs | 22.3 | 30.6 | 24.7 |
| | > 4.5 hrs | 8.7 | 24.1 | 13.1 |
| | Not Reported | 1.1 | 2.8 | 1.6 |
| **Year of Transplant** | 1988 | 27.9 | 0.0 | 19.8 |
| | 1989 | 25.3 | 0.0 | 18.0 |
| | 1990 | 19.6 | 0.0 | 13.9 |
| | 1991 | 19.2 | 0.0 | 13.7 |
| | 1992 | 7.9 | 25.0 | 12.9 |
| | 1993 | 0.0 | 55.6 | 16.1 |
| | 1994 | 0.0 | 19.4 | 5.6 |

**Table VIII-8. Heart-Lung Primary Disease Diagnoses at Time of Transplant**

| |
|---|
| COPD/Emphysema |
| Primary Pulmonary Hypertension |
| Cystic and Idiopathic Fibrosis |
| Alpha-1-Antitrypsin Deficiency |
| Congenital, including Eisenmenger's Syndrome |
| - Congenital Heart Disease |
| - Ventricular and Atrial Septal Defect |
| - Patent Ductus Arteriosus |
| - Multiple Congenital Anomalies |
| - Other Congenital Defects |
| Other Diagnosis |
| - Idiopathic Dilated Cardiomyopathy |
| - Valvular Heart Disease |
| - Inhalation burns/Trauma |
| - Sarcoidosis |
| - Bronchiectasis |
| - Pulmonary Vascular Disease |
| - Other Lung Disease |
| - Retransplant/Graft Failure |
| - Non-Specific |
| - Obliterative Bronchiolitis |
| - Other |

*less than 1* indicates that the characteristic was associated with a *reduced odds* of patient death or graft failure relative to the reference group. An odds ratio of *greater than 1* indicates that the characteristic was associated with an *increased odds* of death relative to the reference group. The corresponding p-value measures how significant the odds ratio is. A p-value less than 0.05 indicates statistical significance and means that there is less than a 5% probability that such difference is due to chance alone. The smaller the p-value, the greater the statistical significance and the less likely the difference is due to chance alone.

**Examples**

In Table VIII-9, the odds ratio of graft failure within 1 year, if the recipient was male, was 1.81. This means that, after adjusting for all of the other donor and recipient characteristics, the odds of graft failure within 1 year was 81% greater for male recipients than for female recipients((1.81-1)×100%=81%). As another example, the odds ratio of graft failure within 1 year post-transplant for a recipient who had a repeat transplant versus a recipient who received a first transplant was 3.91. After adjusting for the effects of both donor and recipient characteristics, the odds of graft failure within 1 year for a patient who had a repeat transplant was 291% higher ((3.91-1)×100%= 291%) than that for a patient who received a first transplant.

The estimated odds ratios for continuous variables (i.e., variables with many possible values) such as cold ischemic time and donor and recipient ages, are less easily interpreted. For these variables, the estimated odds is determined for a set unit increase or decrease from the mean (reference group) of the variable. For example, in Table VIII-9, the estimated odds of 1 month graft failure for 206 minutes of cold ischemic time compared to the mean of 191 minutes is 1.03. This means that, after adjusting for the effects of all other characteristics, the odds of graft failure was estimated to increase by 3% for the first 15 minute increase from the mean cold ischemic time.

An increase of 1 hour (60 minutes) from the mean cold time (i.e., the cold ischemic time is 191 min+60 min=251 min) would result in an 11% increase in the odds of death or graft failure. Mathematically, this 11% was calculated as follows:

$$\text{Odds ratio} = \exp^{\left(\frac{60}{15}\times 0.0260\right)} = 1.11$$

where is 60 the amount of increase in minutes and 15 minutes is the per unit of increase; 0.0260 corresponds to the coefficient of cold ischemic time per 15 minute difference (see Table VIII-12 for coefficients). Therefore, the increase in the odds of death or graft failure is (1.11-1)×100%=11%. For some variables such as recipient age, it is necessary to add a quadratic term. For more details on calculating odds ratios for continuous variables, refer to the section on *Odds Ratios* in the *Technical Methods* chapter of the *Executive Summary*.

## Short Term Graft and Patient Survival

The characteristics with the strongest impact on short term graft and patient survival were having a previous heart-lung transplant and being on a ventilator at time of transplant. The odds of 1 year graft failure was 291% higher if the transplant was a repeat transplant, but was not statistically significant. If a ventilator was used at time of transplant, then the odds of 1 year graft failure was 353% higher than if a ventilator was not being used at time of transplant

**Table VIII-9. Impact of Donor and Recipient Characteristics on Short Term Graft and Patient Survival--Heart-Lung Transplants**

| Short Term Characteristics | Graft Survival | | | | Patient Survival | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Odds Ratio | P-value | Odds Ratio | P-value | Odds Ratio | P-value | Odds Ratio | P-value |
| **Donor Age - 32 vs 22**[1] | 1.148 | 0.628 | 1.168 | 0.783 | 1.137 | 0.589 | 1.158 | 0.783 |
| **Recipient Age - 40 vs 30**[1] | 1.139 | 0.310 | 1.255 | 0.039 | 1.151 | 0.275 | 1.246 | 0.047 |
| **Previous Heart-Lung Transplant: Yes vs No** | 3.357 | 0.122 | 3.907 | 0.132 | 3.836 | 0.118 | 6.996 | 0.092 |
| **On Ventilator at Transplant: Yes vs No** | 6.428 | <0.001 | 4.531 | 0.009 | 6.296 | <0.001 | 4.349 | 0.011 |
| **Recipient Male vs Female** | 1.001 | 0.996 | 1.806 | 0.011 | 0.945 | 0.843 | 1.700 | 0.022 |
| **COPD/Emphysema vs All Others Diagnoses**[2] | n.a.[3] | n.a.[3] | 0.125 | 0.056 | n.a.[3] | n.a.[3] | 0.128 | 0.059 |
| **Cold Ischemic Time - 206 min vs 191 min** [1] | 1.026 | 0.415 | 1.043 | 0.112 | 1.027 | 0.413 | 1.044 | 0.103 |
| **Transplant Year 1990-1994 vs 1988-1989** | 0.716 | 0.276 | 0.401 | <0.001 | 0.697 | 0.244 | 0.400 | <0.001 |

Notes:

[1] Odds ratios for some continuous covariates (donor age, recipient age and cold ischemic time) do not have a linear relationship. The odds ratios presented in this table are 10 or 15 unit increases from the mean of each covariate. The mean donor age was 22. The mean recipient age was 30. The mean cold ischemic times was 191 minutes.

[2] See Table VIII-8 for a listing of heart-lung diagnoses.

[2] Not able to calculate since all recipients with COPD/Emphysema were still alive 1 month after transplant.

## G. LONG TERM SURVIVAL -- IMPACT OF DONOR AND RECIPIENT CHARACTERISTICS

In this report, *long term* survival analyses were developed separately from the short term survival analyses. Because this narrative focuses on conditional 3 year survival (survival at 3 years for grafts or patients surviving at least 1 year post-transplant), only conditional 3 year survival data are presented in this text. Both conditional and unconditional 3 year survival rates are provided in the tables for each transplant program presented in each organ specific volume. The conditional 3 year survival analyses provide an assessment of the donor and recipient characteristics that are independent of those limited to the first year (e.g., surgical complications). The impact of each donor and recipient characteristic on graft and patient long term survival is listed in Table VIII-10.The following characteristics and reference groups were used for *long term graft and patient* survival:

- Medical Condition at Transplant -- not hospitalized
- Mean Cold Ischemic Time -- 191 minutes
- Primary Pulmonary Hypertension -- all other diagnoses
- Year of Transplant -- 1988-1990

### Graft and Patient Survival

The characteristics with the strongest impact on long term graft and patient survival were medical condition at transplant, cold ischemic time and diagnosis at time of transplant. The odds of conditional 3 year graft failure was 169% higher if the patient was in the ICU at time of transplant compared to being not hospitalized at transplant. Having a diagnosis of primary pulmonary

**Table VIII-10. Impact of Donor and Recipient Characteristics on Long-Term Graft and Patient Survival -- Heart-Lung Transplants**

| Long Term Characteristics | Graft | | Patient | |
|---|---|---|---|---|
| | Odds Ratio | P-value | Odds Ratio | P-value |
| Hospitalized vs Not Hospitalized | 3.085 | 0.077 | 2.737 | 0.139 |
| In ICU vs Not Hospitalized | 2.697 | 0.076 | 2.956 | 0.054 |
| Cold Ischemic Time - 206 min vs 191 min [1] | 0.869 | 0.015 | 0.861 | 0.012 |
| Primary Pulmonary Hypertension vs All Other Diagnoses [2] | 2.158 | 0.091 | 1.765 | 0.227 |
| Transplant Year 1991-1992 vs All Other Years | 2.208 | 0.126 | 2.518 | 0.081 |

Notes:

[1] Odds ratios for continuous covariates (cold ischemic time) do not have a linear relationship. The odds ratios presented in this table is a 15 unit increase from the mean cold ischemic time. The mean cold ischemic time was 191 minutes.

[2] See Table VIII-8 for listing of heart-lung diagnoses

hypertension increased the conditional 3 year odds of graft failure 116% compared to any other diagnosis.

## H. COMPARISON BETWEEN SHORT TERM AND LONG TERM CHARACTERISTICS

Except for cold ischemic time and diagnosis, the donor and recipient characteristics that had an impact on short term survival did not appear to have an impact on long term survival.

## I. STATISTICAL METHODS AND MODELS

***This section provides a brief summary of the statistical methods used to determine survival rates for heart-lung transplants, both nationally and at each transplant program. It is <u>not</u> necessary to read this section in order to utilize the rest of the report. For additional statistical details, please see the Technical Methods chapter in the Executive Summary.***

### <u>Model Significance -- $R^2$</u>

The conclusion that there is a "center effect" in heart-lung transplantation often is based on the observation that actual survival rates vary considerably among heart-lung transplant programs. However, in reality, only part of the variability can be attributed to the quality of the program (the so called "center effect"); the rest can be attributed to the differences in donor and recipient characteristics among transplant programs. The degree to which the variability in actual survival rates can be attributed to the specific donor and recipient characteristics in each analysis appears in Table VIII-11.

In the table, the values in the column labeled $R^2$ estimate the percentage of variability in the actual survival rates that can be attributed to the covariates in each analysis. *The higher the percentage, the better the analysis explained the individual program outcomes, based on the characteristics examined.* Theoretically, if an analysis contained every covariate that affected survival outcomes, and there were no differences in quality among programs (i.e., no "center effect"), then $R^2$ would equal 100%. In practice, we can never capture every factor that affects outcomes, and it is likely that real differences among programs do exist. This means that any unexplained variation can probably be attributed to a combination of true center effect and covariates not considered in this study. (For details on the $R^2$ calculation, refer to the *Model Significance* section in the *Technical Methods* chapter of the *Executive Summary*. )

The value of $R^2$ estimated from analyses in the 1994 Report was compared to the value of the $R^2$ analyses in the 1997 Report. Note that these analyses are not

**Table VIII-11. Heart-Lung Model $R^2$: Comparison of the 1994 and 1997 Reports**

| | Time Point | Report Year | Number of Covariates | $R^2$ |
|---|---|---|---|---|
| Graft Model $R^2$ | 1 Month | 1997<br>1994 | 9<br>7 | 14<br>42 |
| | 1 Year | 1997<br>1994 | 9<br>7 | 18<br>28 |
| | Cond. 3 Year* | 1997<br>1994 | 5<br>NA | 49<br>NA |
| Patient Model $R^2$ | 1 Month | 1997<br>1994 | 9<br>7 | 15<br>42 |
| | 1 Year | 1997<br>1994 | 9<br>7 | 19<br>28 |
| | Cond. 3 Year* | 1997<br>1994 | 5<br>NA | 51<br>NA |

* Conditional 3 year analysis was not performed in the 1994 report

*directly* comparable since each was used with a different cohort of transplants. Despite the refinements in the 1997 Report, as compared to the 1994 Report, much of the variation in actual survival rates among the 58 transplant programs in the study remains unexplained by the analyses. This suggests that much of the risk involved in transplantation is due to characteristics not described in this report.

**Estimated Coefficients and Standard Errors from the Logistic Regression Models**

Tables VIII-12 and VIII-13 list the coefficients and the standard errors of the coefficients at each time point for all of the donor and recipient characteristics used in the logistic regression models. Each coefficient is reported on the logistic scale and represents the $\log_e$ odds of graft failure or the $\log_e$ odds of patient mortality for the corresponding characteristic at the specified time after transplant. The adjusted odds ratio on the probability scale may be obtained by applying the exponential function to the coefficient. For further details, see the *Odds Ratios* section in the *Technical Methods* chapter of the *Executive Summary*.

**Expected Heart-Lung Transplant Survival Rates**

Table VIII-14 shows the 1 year *expected graft* survival rates for heart-lung transplants for a given set of donor and recipient characteristics; Table VIII-15 shows the 1 year *expected patient* survival rates. These rates were determined using the following characteristics: recipient age, diagnosis, gender and ventilator status at transplant. For these analyses, all other characteristics were set to the values for the reference groups, with the exception of the year of transplant (1993). The complete list of reference groups is shown on page 130.

For example, in Table VIII-14, the expected 1 year graft survival for a 40 year old male recipient with a diagnosis of COPD and not on a ventilator was 97%. In contrast, the expected 1 year graft survival for a male heart-lung recipient of the same age, with COPD and on a ventilator was 88%.

## J. SUMMARY

**Study Period**

The 1997 Report was based on 373 heart-lung transplants performed in 370 patients between January 1, 1988, and April 30, 1994, from 58 transplant programs in the United States. In order to assess changes within transplant programs over time, the data were divided into 2 eras. The first era included transplants performed from January 1,

**Table VIII-12. Model Coefficients and Standard Errors for Donor and Recipient Risk Characteristics in Short Term Heart-Lung Transplant Survival**

| Short Term Characteristics | Graft Survival | | | | Patient Survival [1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month | | 1 Year | | 1 Month | | 1 Year | |
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| **Intercept** | -1.488 | 0.285 | -0.522 | 0.230 | -1.474 | 0.286 | -0.503 | 0.231 |
| **Donor Age - Linear (per 10 years)[1,2]** | 0.154 | 0.154 | -0.004 | 0.124 | 0.134 | 0.156 | -0.023 | 0.124 |
| **Donor Age - Quadratic (per 10 years)[1,2]** | -0.016 | 0.096 | 0.159 | 0.077 | -0.005 | 0.097 | 0.170 | 0.078 |
| **Recipient Age - Linear (per 10 years)[1]** | 0.130 | 0.128 | 0.227 | 0.110 | 1.141 | 0.129 | 0.220 | 0.111 |
| **Previous Heart-Lung TX: Yes vs No** | 1.211 | 0.784 | 1.363 | 0.905 | 1.345 | 0.859 | 1.945 | 1.154 |
| **On Ventilator at Transplant: Yes vs No** | 1.861 | 0.530 | 1.511 | 0.576 | 1.840 | 0.534 | 1.470 | 0.577 |
| **Recipient Male vs Female** | 0.001 | 0.285 | 0.591 | 0.231 | -0.057 | 0.288 | 0.530 | 0.232 |
| **COPD/Emphysema vs All Other Diagnoses [3]** | n.a.[4] | n.a.[4] | -2.077 | 1.089 | n.a.[4] | n.a.[4] | -2.054 | 1.088 |
| **Cold Ischemic Time (per 15 minutes)[1]** | 0.026 | 0.032 | 0.042 | 0.026 | 0.026 | 0.032 | 0.043 | 0.026 |
| **TX Year 1990-1994 vs 1988-1989** | -0.335 | 0.307 | -0.914 | 0.254 | -0.362 | 0.310 | -0.915 | 0.255 |

Notes:

1 In the analysis, the continuous covariates (donor age, recipient age, cold ischemic time) were centered at their mean. The mean donor age was 22, the mean recipient age was 45 and the mean cold ischemic time was 163 minutes.

2 Modeling the continuous covariates with a linear and quadratic term (the square of the linear term) is necessary due to the relationship between the covariate and the odds of graft failure or patient death.

3 See Table VIII-8 for a listing of heart-lung diagnoses.

4 Not able to calculate since all recipients with COPD/Emphysema were still alive 1 month after transplant.

**Table VIII-13. Model Coefficients and Standard Errors for Donor and Recipient Characteristics in Long Term Heart-Lung Transplant Survival**

| Long Term Characteristics | Graft | | Patient | |
|---|---|---|---|---|
| | Model Coeff. | Std. Error | Model Coeff. | Std. Error |
| **Intercept** | -2.361 | 0.404 | -2.407 | 0.416 |
| **Hospitalized vs Not Hospitalized** | 1.127 | 0.638 | 1.007 | 0.680 |
| **In ICU vs Not Hospitalized** | 0.992 | 0.560 | 1.084 | 0.563 |
| **Cold Ischemic Time (per 15 minutes)[1]** | -0.140 | 0.058 | -0.150 | 0.060 |
| **Primary Pulmonary Hypertension vs All Other Diagnoses[2]** | 0.769 | 0.455 | 0.568 | 0.470 |
| **Transplant Year 1991-1992 vs All Other Years** | 0.792 | 0.518 | 0.924 | 0.530 |

Notes:

1 In the analysis, the continuous covariate cold ischemic time, was centered about its mean. The mean cold ischemic time was 163 minutes.

2 See Table VIII-8 for a listing of heart-lung diagnoses.

**Table VIII-14. Expected U.S. 1 Year Graft Survival Rates -- Heart-Lung Transplants Stratified by Recipient Age, Diagnosis, Gender and Ventilator Status**

| Age | Diagnosis | Male | | Female | |
|---|---|---|---|---|---|
| | | No Ventilator | Ventilator | No Ventilator | Ventilator |
| 5 | COPD/Emphysema* | NA | NA | NA | NA |
| | Other Diseases | 88.1 | 62.1 | 80.4 | 47.5 |
| 25 | COPD/Emphysema | 97.4 | 89.2 | 95.4 | 82.1 |
| | Other Diseases | 82.5 | 50.9 | 72.3 | 36.5 |
| 40 | COPD/Emphysema | 97.1 | 88.1 | 94.9 | 80.4 |
| | Other Diseases | 80.8 | 48.1 | 69.9 | 33.9 |
| 50 | COPD/Emphysema | 96.4 | 85.5 | 93.7 | 76.5 |
| | Other Diseases | 77.0 | 42.5 | 64.9 | 29.0 |
| 60 | COPD/Emphysema | 95.5 | 82.4 | 92.2 | 72.2 |
| | Other Diseases | 72.7 | 37.0 | 59.6 | 24.6 |

* - Disease category not applicable to this age group.

**VIII-15. Expected U.S. 1 Year Patient Survival Rates -- Heart-Lung Transplants Stratified by Recipient Age, Diagnosis, Gender and Ventilator Status**

| Age | Diagnosis | Male | | Female | |
|---|---|---|---|---|---|
| | | No Ventilator | Ventilator | No Ventilator | Ventilator |
| 5 | COPD/Emphysema* | NA | NA | NA | NA |
| | Other Diseases | 87.7 | 62.2 | 80.8 | 49.2 |
| 25 | COPD/Emphysema | 97.3 | 89.2 | 95.5 | 82.9 |
| | Other Diseases | 82.2 | 51.5 | 73.1 | 38.4 |
| 40 | COPD/Emphysema | 97.0 | 88.1 | 95.0 | 81.3 |
| | Other Diseases | 80.5 | 48.7 | 70.8 | 35.8 |
| 50 | COPD/Emphysema | 96.3 | 85.6 | 93.8 | 77.8 |
| | Other Diseases | 76.8 | 43.3 | 66.1 | 31.0 |
| 60 | COPD/Emphysema | 95.4 | 82.7 | 92.4 | 73.7 |
| | Other Diseases | 72.7 | 38.0 | 61.0 | 26.5 |

* - Disease category not applicable to this age group.

Table VIII-16. Comparison of 1 Month and 1 Year Actual Survival Rates Between Eras

| | 1 Month | | 1 Year | |
|---|---|---|---|---|
| | Era 1 | Era 2 | Era 1 | Era 2 |
| Graft Survival (%) | 82.2% | 81.3% | 61.9% | 58.5% |
| Average No. of Transplants/Month | 5 | 5 | 5 | 5 |
| Patient Survival (%) | 82.5% | 81.3% | 61.9% | 58.7% |
| Average No. of Patients/Month | 5 | 5 | 5 | 5 |

1988, through April 30, 1992; the second era covered the two year time period from May 1, 1992, through April 30, 1994.

Survival Rates

Survival rates were computed at 1 month, 1 year, and 3 years, both nationally and for each transplant program. Three year survival was determined in two ways: (1) conditional 3 year survival (i.e., survival at 3 years for those who survived at least 1 year post-transplant), and (2) unconditional 3 year survival. The emphasis is on the conditional 3-year survival rates because the conditional 3-year analysis assesses characteristics independent of those limited to the first year (e.g., surgical complications and early acute rejection events).

The national graft and patient survival rates and completeness of follow-up at 1 month, 1 year, and conditional 3 years are shown in Tables VIII-1 and VIII-2. The percent of programs with graft and patient follow-up data at 1 year was 98%; at conditional 3 years the percent of programs with follow-up data was almost 97%.

The number of heart-lung transplants remained stable from Era 1 to Era 2. As demonstrated in Table VIII-16, there was an average 5 heart-lung transplants per month in each era. For the majority of transplant programs, the difference between actual and expected survival rates was not statistically significant (See Figures VIII-1 and VIII-3). In general, large differences (either higher or lower) were nearly always found among programs that reported relatively few transplants (see Figure VIII-2). Therefore, when evaluating survival rates for a program, it is also important to consider the number of transplants performed.

Differences Between Short Term and Long Term Characteristics

The 1997 Report includes an extensive list of characteristics that have a significant impact on both short and long term graft and patient survival.

Characteristics with the strongest impact on *short term survival* were:

- Recipient age
- Recipient gender
- Recipient on ventilator at transplant
- Year of transplant

Characteristics with the strongest impact on *long term survival* were:

- Recipient in ICU at transplant
- Cold ischemic time
- Year of transplant

## K. FINAL WORDS

The purpose of this report is to provide updated information on survival outcomes both nationally and at specific transplant programs, and to enhance the awareness of program performance in the U.S. However, the assessment of a transplant program should not be based solely on the survival rates provided in this report. Some of the other important factors to consider are the experience of the transplant team, support personnel, the cost of the procedure, and the quality and location of post-transplant services.

# IX. TECHNICAL METHODS

Cohort
Definitions of Survival Time and Complete Follow-Up
Actual Survival Rates
Expected Survival Rates
Testing for Significance of Program Effects
Calculation of $R^2$
Odds Ratio
Calculation of Individual Expected Survival Rates
Technical Oversight Committee

# IX. TECHNICAL METHODS

This chapter provides details of the technical methods used in preparing this report. Sections A through F, written on a slightly more rigorous level than the preceding chapters, are intended for readers with a basic/some knowledge of epidemiology and statistics. Sections G and H illustrate how to calculate odds ratios and the expected survival rate for an individual. Section I lists the members of the Technical Oversight Committee for this study.

## A. COHORT

A total of 97,587 transplants performed at 742 U.S. transplant programs between January 1, 1988 and April 30, 1994 were included in the study to calculate national and center specific graft and patient survival rates.

The entire cohort was analyzed to determine short term survival rates at 1 month (or 3 months for abdominal organs) and 1 year. A subset of the cohort, i.e., all transplants performed between January 1, 1988 and April 30, 1992, was used to determine long term survival rates at 3 years, which was defined in two ways:

- survival at 3 years post-transplant, and
- survival at 3 years post-transplant for those who survived at least 1 year, referred to as **conditional 3 year survival.**

Exclusions

All multiorgan (except kidney-pancreas and heart-lung) transplants, heterotopic heart transplants, and living donor (except kidney) transplants were excluded.

## B. DEFINITIONS OF SURVIVAL TIME AND COMPLETE FOLLOW-UP

Survival Time

Transplants for which the reported graft status was "Failed" were counted as graft failures on the date of failure, and those with "Functioning" status were counted as functioning on the date of follow-up.

For kidney transplants, if the graft status was "Impaired," it was counted as "Functioning," but for pancreas transplants, if the status was "Partial Functioning," it was counted as "Failed."

In addition, in the short term (i.e. 3 month and 1 year) analyses, kidney or pancreas transplants for recipients who were reported to have "Died with a functioning graft" were treated as graft failures at the time of death. ***In the conditional 3 year analysis, death with a functioning kidney or pancreas*** was treated as censored or "Functioning" at the time of death because it is more likely that, in the long term, death might not be related to the transplant procedure.

Graft survival time was calculated as the number of days from the transplant date to:
1) the date of graft failure, or
2) if graft failure was not reported, the date of death, or,
3) if death was not reported, the date of follow-up.

Similarly, patient survival time was calculated as the number of days from the transplant date to:
1) the date of death, or
2) if death was not reported, the date of follow-up.

Complete Follow - up

For survival analysis, follow-up indicators were created for each transplant and time interval considered below. The criteria for complete graft (patient) follow-up are described as follows:

| Interval | Complete Follow-up Definition |
|---|---|
| 0-1 month: | A graft failure (patient death) between 0 and 30 days from the transplant date, or a functioning graft (patient alive) at 30 days or more. |
| 0-3 months: | A graft failure (patient death) between 0 and 90 days from the transplant date, or a functioning graft (patient alive) at 90 days or more. |
| 0-1 year [1]: | A graft failure (patient death) between 0 and 365 days from the transplant date, |

or a functioning graft (patient alive) at **330** days or more.

conditional 3 years [1, 2]: A graft failure (patient death) between 366 and 1095 days from the transplant date, or a functioning graft (patient alive) at **1060** days or more for the cohort of transplants between January 1, 1988 and April 30, 1992.

## C. ACTUAL SURVIVAL RATES

The binomial method was used to compute the transplant program actual graft and patient survival rates at each time point. The actual survival rate (%) at time *t*, $t$=1 month or 3 months, 1 year, or 3 years, for a transplant program is computed as:

$$\frac{N_{\text{survived,t}} + A_t}{N_{\text{failed,t}} + N_{\text{survived,t}} + A_t} \times 100$$

where the terms $N_{\text{failed,t}}$ is the number of grafts that failed (patients died) within and up to the end of the interval, $t$ and $N_{\text{survived,t}}$ is the number of grafts (patients) that survived beyond time, $t$. The term $A_t$, both in the denominator and numerator, is incorporated to adjust for the fact that some of the transplants (patients) were lost to follow-up before time $t$ (referred to as incomplete follow-up). Specifically, $A_t$ is the *weighted* number of grafts (patients) with *incomplete* follow-up, where the weight equal to the proportion of time in the interval the graft (patient) was still functioning (alive). This weight is fractional for those grafts (patients) with *incomplete* follow-up data. In contrast, the weight for those grafts (patients) that had complete follow-up data would always equal 1.

**Example**
In the one year graft survival analysis, if a graft was last reported as functioning at 9 months after transplant, the weight would be 9/12=.75 for that graft. *The earlier a graft was lost to follow-up, the smaller the weight would be.*

### More on Patient Survival Rates

Patient survival rates were calculated in a similar manner as graft survival rates. However, if a patient received more than one transplant of the same organ type, in estimating *center specific patient* survival rates, it is more appropriate to account for all the transplants the patient had than to consider only his or her first transplant. This is because the patient might have been transplanted at more than one center, and in this case, the patient's survival outcome should be attributed to more than one center.

For patients who had $n$ transplants during the period of analysis (i.e., 1/1/88-4/30/94), the survival time for each transplant would be the time between the corresponding transplant date and the most recent follow-up date or the death date. To avoid over-weighting such a patient in the analysis of patient survival, each transplant was weighted by a factor equal to $1/n$. If transplant follow-up was not complete through the end of the time interval, the transplant was weighted by $1/n$ multiplied by the proportion of time for which there was follow-up data.

**Example**
Suppose Patient A had his first transplant on 1/1/91 and his second transplant on 7/1/91, and was still alive on 1/1/92. The follow-up time for the first transplant would receive a weight of (½)×(1)=½. However, the second transplant would receive a weight of (½)×(6/12)=1/4. Because the patient received two transplants, each transplant received a weighted factor of $1/n$ or ½, where $n$ equals the number of transplants. The first transplant had complete follow-up data available for the 1 year survival analysis, therefore, the second term (1) indicates that complete follow-up data were available. For the second transplant, there were only 6 months of available follow-up time so the second term (6/12) indicates that 6 out of 12 months of follow-up data were available. Note that the total weight for a patient does not necessarily equal 1.

---

[1] Graft failure (patient death) takes precedence when determining survival outcomes. For example, if a graft failed at day 345, even though the graft was functioning at some point during the window for follow-up, it is considered a failure rather than being functioning at 1 year.

[2] The time interval for the conditional 3 year analysis was from 1 year to 3 years post transplant.

More on 3 Year Survival Rates

In each center specific survival table, the unconditional 3 year survival rate was also reported for the period of January 1, 1988 and April 30, 1992. Following the Bayes rule (a well known statistical formula), the unconditional 3 year survival rate was simply computed as the product of the conditional survival at 3 years and the net survival at 1 year. For instance, if the 1 year and the conditional 3 year survival rate are 80% and 70%, respectively, the unconditional 3 year survival rate would be 56%.

*Caveat*

The 1 year *expected* survival rate was based on the data from the entire cohort, i.e., January 1, 1988 through April 30, 1994. The conditional 3 year *expected* survival rate was based on the data from January 1, 1988 through April 30, 1992 only.

More on Death With Functioning Graft

In the one year analysis, death with a functioning *kidney* or *pancreas* was considered as graft failure. However, in the conditional 3 year analysis, they were considered as censored observations. The unconditional 3 year survival rate could be lower if death with a functioning *kidney* or *pancreas* was treated the same as graft failure in both the 1 year and conditional 3 year analyses, or higher if death with a functioning *kidney* or *pancreas* was treated the same as censored observation in both the 1 year and conditional 3 year analyses. Nevertheless, the center effect, i.e., the difference between actual and expected survival rates should be similar because the same convention is used for death with a functioning graft in the calculation of both actual and expected survival rates.

Comparison with Kaplan-Meier Survival Rates

Typically, survival data are analyzed using the Kaplan-Meier (K-M) method. The binomial method is a simple alternative to the K-M method, particularly when there is a high degree of completeness of follow-up data. It was chosen for computing actual survival rates in this report because it is a natural counterpart to logistic regression, which was used to determined the expected survival rates.

Using the weights described earlier in this section, the binomial survival rates were nearly identical to Kaplan Meier survival rates (see Table IX-1).

**Table IX-1. Overall Graft and Patient Survival Rates Using Binomial Method (Kaplan Meier Survival Rates are in Parentheses).**

| Organ | Graft Survival % | | | Percent Patient Survival % | | |
|---|---|---|---|---|---|---|
| | 1 or 3 Months | 1 Year | Cond. 3 Years | 1 or 3 Months | 1 Year | Cond. 3 Years |
| Kidney | 88.8 (88.8) | 83.4 (83.5) | 90.8 (90.8) | 97.2 (97.2) | 94.3 (94.2) | 94.5 (94.1) |
| Liver | 77.7 (77.7) | 69.9 (69.9) | 89.0 (89.0) | 85.3 (85.7) | 79.0 (79.9) | 90.4 (91.8) |
| Pancreas | 83.6 (83.6) | 73.5 (73.6) | 91.3 (91.2) | 96.1 (96.1) | 91.1 (91.2) | 92.3 (92.2) |
| Heart | 91.6 (91.4) | 81.7 (81.7) | 90.2 (90.2) | 92.1 (91.7) | 82.5 (82.2) | 90.7 (90.9) |
| Lung | 86.8 (86.6) | 70.4 (70.5) | 74.7 (74.7) | 87.7 (87.1) | 71.9 (71.3) | 75.9 (77.5) |
| Heart-Lung | 81.9 (82.0) | 61.9 (62.1) | 80.1 (80.1) | 82.2 (82.2) | 61.9 (62.1) | 81.2 (81.3) |

## D. EXPECTED SURVIVAL RATES

### Model-Fitting

Separate graft and patient survival models were fit to the national data for each organ and time point using logistic regression with selection of covariates through backward elimination.[3] For the kidney and liver analyses, the significance level for a covariate to remain in the model was 0.05; due to small sample size, 0.15 was used as the significance level for the pancreas analyses and for the heart-lung conditional 3 year analysis. A significance level of 0.10 was used for the remaining analyses.

In general, continuous covariates were centered about their means and initially were modeled with both a linear and a quadratic term. If the quadratic term of a continuous covariate remained in the model, the linear term was forced to remain in the model as well (regardless of the p-value of the linear term). For categorical covariates with $k$ levels, $k$-1 levels were modeled as indicator variables, with the remaining level serving as the baseline. The baseline category was often chosen to be the largest category.

Using the conventions established for the 1994 Center Specific Report, the final *graft* and *patient* survival models for liver, heart, heart-lung, and lung transplants at each time point contained the same covariates. Any covariate that appeared in the final models for *either* graft or patient survival was included in *both* the graft and patient survival models for these organs. Because graft and patient survival are markedly different for kidney and pancreas transplants, the above convention was not adopted in determining the final graft and patient survival models for these two organs. For all organs, any covariate that appeared in the final models for *either* 3 month or 1 year survival was included in *both* the 3 month and 1 year survival models; however, the models for conditional 3 year survival could contain different covariates.

### Missing Observations and Data Imputation

Missing values for any covariate were set to the baseline value for that covariate, with a few exceptions. In the kidney data, depending on the type of donor, a missing cold ischemic time was set to the corresponding mean value for either living donor transplants or cadaveric donor transplants. If level of mismatch could not be determined at either the A, B or the DR locus, then the overall mismatch level for that observation was be considered to be missing. In the analysis, the total mismatch level for these observations would be incremented by one for each locus at which the mismatch level could not be determined. If the level of PRA was missing, it was reset to the median value.

Recipient body mass index was computed as $W/H^2$, where W=recipient weight in kilograms and H=recipient height in meters. If height was missing, it would be imputed according to a regression equation that was estimated using nonmissing gender and age:

Male:

$$H = 1.754 - 0.983 \times e^{-(0.009 \times age + 0.0066 \times age^2)},$$

Female:

$$H = 1.616 - 0.923 \times e^{-(0.038 \times age + 0.0066 \times age^2)}.$$

Alternatively, if weight was missing, it would be imputed using height, gender and age:

Male:

$$W = 31.688 + 1.151 \times age - 0.013 \times age^2 + 0.00003 \times age^3 - 58.208 \times H + 39.013 \times H^2$$

Female:

$$W = 17.667 + 0.771 \times age - 0.003 \times age^2 - 0.00005 \times age^3 - 33.967 \times H + 30.315 \times H^2$$

### Outliers in the Covariates

Adjustments were made to ensure that aberrant observations did not unduly influence the fitted estimates for parameters corresponding to continuous covariates.

[3] PROC LOGISTIC of SAS, version 6.12 (SAS Institute, Cary, NC)

In determining the kidney models, reported values of cold ischemic time greater than 72 hours for cadaveric donor transplants were reset to 72 hours. Reported values of cold ischemic time greater than 8 hours for living donor transplants were reset to 8 hours. Any body mass index that exceeded the range of 10 to 55 were reset to 10 or 55, as appropriate.

In determining the liver and pancreas models, reported values of cold ischemic time greater than 33 hours and 38 hours, respectively, were reset to 33 hours and 38 hours. In determining the heart models, reported values of cold ischemic time less than 30 minutes were reset to 30 minutes.

**Model Interactions**

Due to the lack of substantial evidence in the transplant literature to warrant their investigation, specific interactions among main effects were not considered.

**Transplant Program Expected Survival Rates**

As with the actual survival rate, the expected graft (patient) survival rate at the end of the time interval, $t$, for a particular transplant program, would be the weighted average of the expected survival probabilities for each transplant (patient) at the end of the interval, $t$, where the expected survival probabilities were obtained from the logistic models and weights were as defined in Section C of this chapter.

## E. TESTING FOR SIGNIFICANCE OF PROGRAM EFFECTS

A score statistic[4] was used to test for the significance of transplant program effects. Let $\gamma$ be the vector of model parameters, and let $D(\gamma)$ be the vector of partial derivatives of the log likelihood with respect to the parameter vector $\gamma$.

$$\gamma=(\alpha,\beta_1,...,\beta_k,\beta_{k+1}),$$

where $\alpha$ is the intercept term, $\beta_1,...,\beta_k$ are the donor and recipient risk factor covariates and $\beta_{k+1}$ is the indicator covariate for a particular transplant program.

Let $\hat{\alpha},\hat{\beta}_1,...,\hat{\beta}_k$ denote the maximum likelihood estimates of the model intercept $\alpha$ and the covariates $\beta_1,...,\beta_k$. Under the null hypothesis of no transplant program effect,

$$\gamma_0=(\hat{\alpha},\hat{\beta}_1,...,\hat{\beta}_k,0),$$

so that the quantity

$$\chi_s^2=D(\gamma_0)I^{-1}(\gamma_0)D'(\gamma_0)$$

where $I^{-1}(\gamma_0)$ is the matrix of the negative second partial derivatives of the log likelihood with respect to $\gamma_0$, has an asymptotic chi-square distribution with one degree of freedom. The two-sided p-value for the transplant program effect is then

$$P(\chi_1^2>\chi_s^2).$$

For example, if the chi-square statistic for a particular transplant program was 2.36, then the corresponding p-value would be $P(\chi_1^2>2.36)=0.12$.

A chi-square statistic of 3.86 corresponds to a p-value of 0.05. Thus a chi-square statistic greater than 3.86 which has a p-value less than 0.05 is often referred to as statistically significant.

When the number of transplants performed at a transplant program is too small, the proposed chi-square test is not appropriate because the asymptotic theory does not necessarily hold with small sample size. In cases where the number of transplants for a transplant program is less than six, the p-value for that transplant program effect was obtained from a binomial distribution. This p-value is based on $n_j$ (the number of transplants (patients) at time $t_j$) and $p_j$ (the expected graft (patient) survival rate), for $j=1$ or 3 months, 1 year and 3 years. By assuming that $X_j \sim B(n_j, p_j)$ where $x_j$ is the number of failures (deaths) in the $j$th time interval, $x_j = 0, 1, 2, 3, 4, 5$, the p-value for the transplant program effect can be computed as defined below.

If $x_j \geq n_j / 2$,

$$\text{p-value} = \min\{(P(X_j \geq x_j) + P(X_j \leq n_j - x_j)), 1\}.$$

[4] Agresti, A. 1990. *Categorical Data Analysis.* New York: Wiley.

If $x_j < n_j / 2$,

$$\text{p-value} = \min \{ (P(X_j \le x_j) + P(X_j \ge n_j - x_j)), 1 \}.$$

The method of determining the p-value for the transplant program effect for patient survival is analogous.

## F. CALCULATION OF $R^2$

This quantity is a measure (percentage) of how much of the program-to-program variation in actual survival rates is explained by each logistic regression model and applies to transplants and programs for each organ type.

Let $A_i$ denote the actual survival rate and let $E_i$ denote the expected survival rate for the $i$th transplant program. Let $\bar{A}$ be the average of the actual survival rates over all $k$ transplant programs, computed as

$$\bar{A} = \frac{1}{k} \sum_{i=1}^{k} A_i$$

Let $V_i$ denote the approximate variance of the difference between the actual and expected survival rates for the $i$th transplant program. We used $V_i \cong \frac{(A_i - E_i)^2}{\chi_s^2}$. Note that $V_i^{-1}$ is used as a weight for each term of the summation in the equation below. This prevents the results for smaller volume programs from unduly influencing the calculation. Then for a given model, the percent reduction in variance was defined as

$$R^2 = 1 - \frac{\sum_{i=1}^{k} V_i^{-1} (A_i - E_i)^2}{\sum_{i=1}^{k} V_i^{-1} (A_i - \bar{A})^2}.$$

In this report, $R^2$ is expressed as a percentage and the values of the $R^2$ are presented in Table 11 of each organ specific summary chapter (Table 10 for pancreas).

### C Statistic

As mentioned, $R^2$ is a measurement of how the program-to-program variation in actual survival rates is explained by each logistic regression model. It is, however, not a good indication of the predictive ability of a logistic regression model in general. A better way of assessing how well the model predicts an individual's expected probability is to use the $C$ statistic[5], also known as the area under the receiver-operating-characteristic (ROC) curve. In theory, values for $C$ range from 0.5 to 1, with 1 corresponding to a model that has perfect prediction.

The $C$ statistics for the models considered in this report are presented in Table IX-2. Their values range from 0.585 for the 1 year patient survival model for pancreas to 0.719 for the conditional 3 year patient survival model for heart-lung. Because these values are not very close to 1, this suggests that there are factors not included in the models that might improve the prediction. Most important of which may be transplant programs related factors (i.e. center effects), such as transplant volume.

## G. ODDS RATIO

In this report, the term "odds ratio" is used to compare the impact of two risk factors on graft and patient survival. Its concept is similar to "relative risk" which is the risk of one event relative to another and is also commonly used in statistical analyses.

For two events, let $\theta_1$ denote the probability of event one and let $\theta_2$ denote the probability of event two. The odds is defined as $\theta_i/(1-\theta_i)$, $I$=1,2, meaning the chance of one event occurring relative to the chance of the same event not occurring. The odds-ratio of event one relative to event two is defined as:

$$\frac{\theta_1/(1-\theta_1)}{\theta_2/(1-\theta_2)}.$$

[5] Cox D.R. and Wermuth N. 1992. A comment on the coefficient of determination for binary responses. *Am Stat* 46:1-4.

**Table IX-2. *C* Statistics.**

| Organ | Graft Survival (%) | | | Patient Survival (%) | | |
|---|---|---|---|---|---|---|
| | 1 or 3 Months | 1 Year | Cond. 3 Years | 1 or 3 Months | 1 Year | Cond. 3 Years |
| Kidney | 0.664 | 0.663 | 0.689* | 0.707 | 0.700 | 0.704* |
| Liver | 0.686 | 0.675 | 0.668 | 0.712 | 0.700 | 0.682 |
| Pancreas | 0.608 | 0.638 | 0.639 | 0.637 | 0.585 | 0.621 |
| Heart | 0.678 | 0.631 | 0.585 | 0.678 | 0.632 | 0.583 |
| Lung | 0.717 | 0.661 | 0.621 | 0.718 | 0.660 | 0.604 |
| Heart-Lung | 0.630 | 0.692 | 0.711 | 0.632 | 0.690 | 0.719 |

* The *C* statistics are based on Model I of Table III-12 and Table III-13. When including the two post-transplant covariates (Model II), the *C* statistics would be 0.697 for graft survival and 0.710 for patient survival.

The odds ratio for dichotomous variables is relatively easy to interpret. For example, "the odds ratio of graft failure at 1 year for repeat kidney transplants was 1.3." means that the odds of graft failure for repeat transplants was 30% higher than the odds of graft failure for primary transplants at 1 year. The reference category (baseline) was primary kidney transplants.

Note that *odds* is not the same as *probability*. The following example will illustrate this concept.

**Example**
Suppose the estimated probability of death at 12 months for repeat kidney transplants was 0.25 and that for primary transplants was 0.20, then the odds ratio is:

$$\frac{(0.25)/(0.75)}{(0.20)/(0.80)} = 1.3$$

When a particular variable is on a continuous scale (referred to as continuous variable), the odds ratio is less easy to interpret. In this report, the odds ratios for continuous variables such as recipient age refers to an unit increase or decrease from the mean of the variable. For example, the odds of graft failure at 1 month for a heart transplant in which the donor heart had a cold ischemic time of 5 hours (300 minutes), relative to that for a transplant in which the donor heart had a cold ischemic time of 163 minutes (the baseline) is calculated as:

$$e^{\left(\frac{300-163}{15}\times 0.0296\right)} = 1.31.$$

In the above calculation, the mean cold ischemic time for heart transplants (163 minutes) serves as the baseline, and 15 minutes is the incremental unit for cold ischemic time. The *logarithm* of the odds of graft failure increases 0.0296 (Table VI-12) for each unit increase beyond the mean. Therefore, the odds of mortality for an increase of (300-163)=137 minutes is 1.31.

Note that, as can be seen in the above equation, odds ratios have an exponential relationship. That is, the increase of the odds ratio is non-linear for any linear increase of the variable. Therefore, caution should be exercised when computing the odds ratios at different values for any continuous variables.

For some continuous variables, such as recipient and donor age, body mass index and peak PRA, a quadratic term was included in the models in additional to the linear term in order to provide a better fit. Similar to the previous example, the odds ratio of 1 year graft failure, for example, between a heart recipient of age 55 and a heart recipient of age 45 is:

$$e^{[(\frac{55-45}{10})\times 0.1404+(\frac{55-45}{10})^2\times 0.0530]}=1.15,$$

where the incremental unit for age is 10 years, and 0.1404 and 0.0530, respectively, correspond to the model coefficients of the linear and quadratic terms of the recipient age (Table VI-12).

## H. CALCULATION OF INDIVIDUAL EXPECTED SURVIVAL RATES

Using Tables 12 and 13 in each organ specific chapter (Tables 11 and 12 for pancreas), one can calculate an individual's expected graft and patient survival rates at 1 month or 3 months, 1 year and conditional 3 years for the time period of 1988 to April of 1994. The steps are:

**Step 1: Calculate X,**

$$X = \beta_0 + \beta_1 \times Z_1 + \beta_2 \times Z_2 + \ldots + \beta_i \times Z_i + \ldots$$

where $\beta_0$ is the coefficient that corresponds to the intercept in each graft (patient) survival model (Tables 12 and 13 or 11 and 12 for pancreas). $\beta_i$ and $Z_i$ are the coefficient and the value that correspond to the *i*th variable, respectively. *If a variable does not apply to the graft (patient) survival model, $Z_i$ simply takes a value of zero.* Furthermore, continuous variables must be centered at their population mean and scaled by the appropriate unit.

**Step 2: Using X, calculate P:**

$$P = \frac{1}{1+e^{X}}$$

P is the individual's expected probability of graft (patient) survival at the time point of interest.

**Example**
Consider the 1 year patient survival rate for a patient who had a heart transplant (Table VI-13). X can be obtained from the following equation:

X= - 2.1587
+ .0830 × [(donor age-26)/10]
+ .0494 × [(donor age-26)/10]$^2$
+ .1432 × (if donor is Black)
+ .2404 × (if donor is Hispanic)
+ .3942 × (if donor is other)
+ .1432 × (if donor is female)
+ .0204 × [( cold time in minutes - 163)/15]
+ .1577 × [(recipient age-45)/10]
+ .0557 × [(recipient age-45)/10]$^2$
- .0426 × (if recipient age=0 or 1)
+ .0906 × (if recipient is female)
+ .1240 × (if recipient in ICU at transplant)
+ .2897 × (if recipient is black)
+ 1.2143 × (if previous heart transplant=Yes)
+ .7099 × (if on ventilator at transplant)
+ .2621 × (if on VAD at transplant)
+ .1534 × (if on IABP at transplant)
+ .0778 × (if recipient had coronary disease)
+ .3104 × (if recipient had congenital disease)
+ .2111 × (if recipient had valvular disease)
+ .0931 × (if recipient had other heart disease, not including cardiomyopathy)
- .1335 × (if transplant year=1993 or 1994)

For instance, for a 50 year old White man who received a primary heart transplant from a 35 year old Black female donor after being in ICU:

X= - 2.1587
+ .0830 × [(35-26)/10]
+ .0494 × [(35-26)/10]$^2$
+ .1432 × 1
+ .2404 × 0
+ .3942 × 0
+ .1432 × 1
+ ...
+ .1577 × [(50-45)/10]
+ .0557 × [(50-45)/10]$^2$
- .0426 × 0
+ .0906 × 0
+ .1240 × 1
+ .2897 × 0
+ 1.2143 × 0
+ ...

Suppose X= - 1.72, then P would be

$$P = \frac{1}{1+e^{-1.72}} = 0.85$$

Therefore, expected probability of 1 year patient survival for this heart recipient would be 85%.

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